Journal Club
PICS-F

東京ベイ・浦安市川医療センター
PGY-2　渡辺　将人

本日の論文

Research

Original Investigation

Effect of Palliative Care–Led Meetings for Families of Patients With Chronic Critical Illness
A Randomized Clinical Trial

Shannon S. Carson, MD; Christopher E. Cox, MD, MPH; Sylvan Wallenstein, PhD; Laura C. Hanson, MD, MPH; Marion Danis, MD; James A Tulsky, MD; Emily Chai, MD; Judith E. Nelson, MD, JD

JAMA. 2016;316(1):51-62.

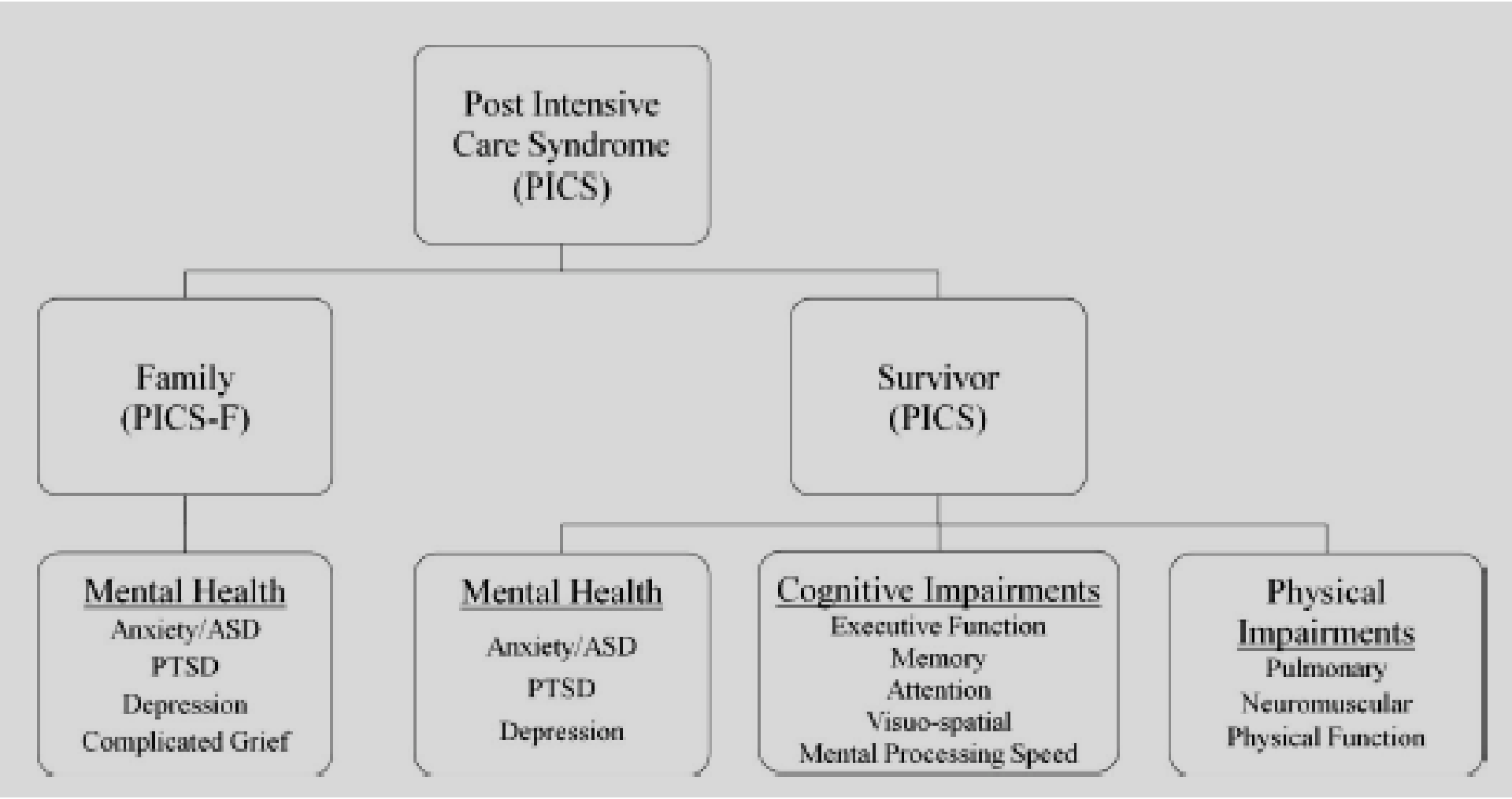
PICS
Post Intensive Care Syndrome

PICS
集中治療後症候群

- 重症疾患後に新しく、または悪化した身体機能、認知機能、メンタルヘルスの障害の総称

- **PICS-F**とは、重症疾患を患った患者の家族に起こるメンタルヘルスの障害のこと

PICS概念図



Crit Care Med 2012; 40:502–509

The NEW ENGLAND JOURNAL of MEDICINE

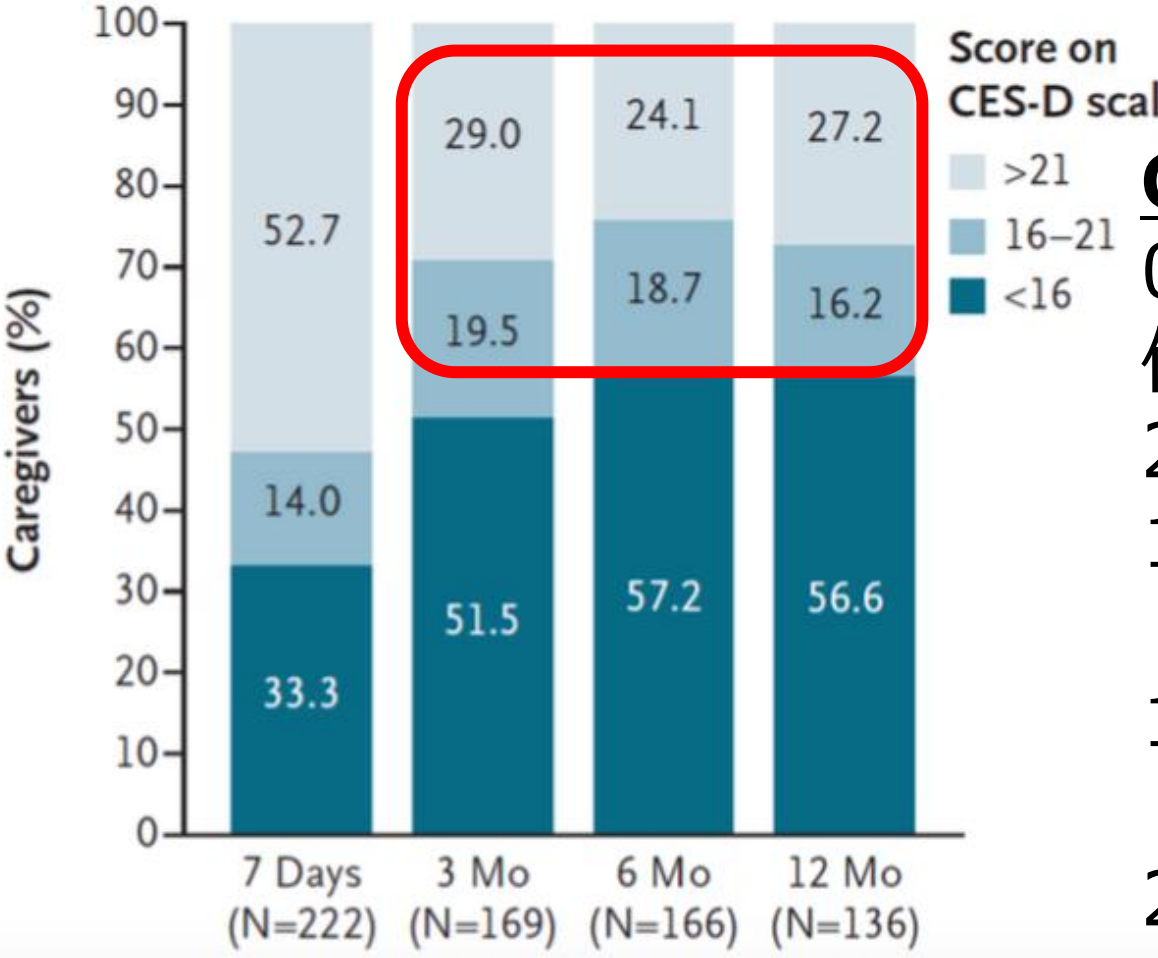
ORIGINAL ARTICLE

One-Year Outcomes in Caregivers of Critically Ill Patients

	多施設前向き観察研究 （カナダの大学病院ICU10施設）
対象	最低7日間人工呼吸管理を受けた ICU生存者の介護者 介護者の定義:無報酬で退院後の患者ケアに責任を負う家族、または友人
アウトカム	介護者のメンタルヘルス

N Engl J Med.2016;374(19):1831-1841.

介護者とうつ病



CES-Dスケール

0-60点で　うつを評価

20問（0～3点）

16点以下は正常

　うつ症状がない

16-21点

　うつのリスクを示唆

21点以上

　うつ状態を示唆

半年後、1年後も、介護者の25%前後はうつ状態

PICS、PICS-Fを防ぐために

- ABCDEバンドル
- F（Family involvement, Follow up referrals, Functional reconciliation）
- G（Good handoff communication）
- H（Handout materials on PICS and PICS-F）

家族とのコミュニケーションとPICS-F

- 長期化した重症患者の予後やゴールについて話し合う際に、意思決定者とのコミュニケーションが不十分なことがしばしばある

  Arch Intern Med. 2007;167(22):2509-2515.
  J Crit Care. 2005;20(1):79-89.

- ICUにおいて、予後やゴールオブケアについてのコミュニケーションを改善させることで、PICS-Fが改善されないか？

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Communication Strategy and Brochure for Relatives of Patients Dying in the ICU

	フランスのICU22施設で行われたRCT
P	数日以内に亡くなる可能性が高いと判断された患者の家族
I	VALUEによる家族カンファレンス +小冊子（死別や葬儀、悲嘆の過程などに関する時系列の情報が記載）
C	Usual practice
O	90日目のIESスコア（PTSDを評価するスコア）

コミュニケーションを改善するための介入

- **VALUEによるコミュニケーション**

①**V**alue and appreciate what the family members said

②**A**cknowledge the family members emotions

③**L**isten

④ask questions that would allow the caregiver to **U**nderstand who the patient was as a person

⑤**E**licit questions from the family members

Table 4. Outcomes Assessed on Day 90.

Variable	Control Group (N=52)	Intervention Group (N=56)	P Value
IES score			0.02
Median	39	27	
Interquartile range	25–48	18–42	
Presence of PTSD-related symptoms (IES score >30) — no. (%)	36 (69)	25 (45)	0.01
HADS score			0.004
Median	17	11	
Interquartile range	11–25	8–18	
Symptoms of anxiety — no. (%)	35 (67)	25 (45)	0.02
Symptoms of depression — no. (%)	29 (56)	16 (29)	0.003
Saw a psychologist after death of patient — no. (%)	6 (12)	4 (7)	0.41
Received newly prescribed psychotropic drugs after death of patient — no. (%)	12 (23)	6 (11)	0.05
Effectiveness of overall information provided — no. (%)			
Time allotted to provide information was sufficient	45 (87)	51 (91)	0.45
Information was clear	45 (87)	52 (93)	0.34
Additional information requested	24 (46)	17 (30)	0.05

PTSD症状は介入群で良好

不安、うつ症状は介入群で良好

意思決定をする時期に
緩和治療医による情報提供や、
精神的なサポートをすることで、
長期化した重症患者をもつ家族の
不安やうつの症状を
減らすことはできないか？

本日の論文

Research

Original Investigation

Effect of Palliative Care–Led Meetings for Families of Patients With Chronic Critical Illness
A Randomized Clinical Trial

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JAMA. 2016;316(1):51-62.

本論文のPICO

- P：７日以上の人工呼吸器管理が必要な重症患者の家族
- Ｉ：緩和治療医師によるミーティング
- C：集中治療医師によるミーティング
- O：90日後のHADSスコア

Design

- 多施設合同ランダム化比較試験
  （アメリカ４施設）

- 期間：2010年10月から2014年11月
- 対象：21歳以上で、内科ICUにおいて７日以上人工呼吸器管理が必要と判断された患者とその意思決定者

Patients

Inclusion criteria	Exclusion criteria
・21歳以上 ・96時間以上中断なく7日以上の人工呼吸器管理が必要 （最初の1年のみ10日間） ・72時間以内に人工呼吸器離脱が予測されない ・72時間以内に死亡が予測されない	・他院で7日以上人工呼吸器管理が行われていた患者 ・慢性の神経筋疾患、外傷、熱傷、中毒者 ・意思決定者が英語が理解できない ・調査者が主治医 ・以前に参加ICUに入院歴がある ・スクリーニング以前にすでに緩和ケア医の介入あり ・介入を拒否した患者 ・すでに気管切開されている患者 ・家族や意思決定者がいない ・家族がday7～21で連絡不能

Randomization Masking

- support and information team（SIT） によるミーティング群
- ICU医師によるミーティング群

- 施設で層別化し、computer-generated, web-based randomization system with blinding of allocation

- open labelだがアウトカム評価はblindされた評価者が行う

Intervention

	SIT （support and information team）	control
共通	慢性重症感者に関するパンフレットを配布	
構成	緩和治療医師・NP 必要に応じて SW・牧師・他分野の専門家	ICU医師
その他	・最低２回のミーティング ・家族の求めや医師が必要と判断した際は追加でミーティング可能 ・事前にICU医とpre meetingを行う。 ・テンプレートに沿って行う	・状況に応じてミーティングを施行 ・緩和ケア医の介入が必要と判断すればコンサルトすることも可能

SITによるmeeting

- **１回目**が人工呼吸器管理を開始し7日後で気管切開が検討される時期
- **２回目**が人工呼吸機離脱した患者の今後の治療方針を決めるおおよその平均期間
- １回目と2回目の間は10日以上空ける
- 家族やICU医、SITメンバーによる要請で、上記に加えてのmeetingを行うことができる

1回目のPre meetingの内容

Date of Hospital Admission: --/--/---- Date of ICU Admission: --/--/----

ICU Admitting Diagnoses

_____

_____

Date when MV was first initiated in this hospitalization (or in transferring hospital): --/--/----

Number of days of MV (without > 48 hrs interruption): ___

Number of failed extubations during this hospitalization (patient reintubated within 1 week): ___

Current FiO_2 on Ventilator: _____ % Requiring vasopressors Y/N _____

ICU MD's Prognostic Estimates: *(transcribe from tablet VAS)*

Ventilator Liberation: _____ 3-Month Survival _____

One-year Survival: _____ Functional Independence: _____

呼吸管理の現状

予後

Patient Treatment Preferences (per ICU MD understanding):

Resuscitation Preference:

□ Attempt resusc □ Do not attempt resusc □ Resusc pref unknown to ICU MD

Advance Directive re Other Treatments:

□ No limitation □ Limitation, specify _____

Insights/Impressions About Primary Surrogate:

ICU Attending MD Plans to Attend SIT-1 Meeting: □Yes □No

Key Participants for SIT-1 Meeting

Family	Relation to Pt	Study Subj (ADM) Y/N

ICU MD's Preliminary Thoughts About Appropriate Care Plan (check all that apply):

- □ Proceed with tracheotomy
- □ Continue MV/intensive care therapy without limitation at this time
- □ Continue with short (≤ 7 days) further trial of MV/intensive care, but readdress goals soon
- □ Exclusive focus on palliative care
- □ Withdraw life-sustaining therapy
- □ Uncertain / Equivocal (check only if no other box is checked)
- □ Other /Additional Comments

今後の治療展開

Other Important Information Discussed with ICU Team/Other Notes

2回目のPre meetingの内容

Number of days of mechanical ventilation (without > 48 hrs interruption): _____

Is patient still dependent (fully or partially) on the ventilator? Yes ____ No _____

If yes, proceed to next 3 items about progress toward ventilator liberation:

1-No. of hours of spontaneous breathing (TC or equiv) within past 24 hrs: _____
2-Current Ventilator Settings: _____
3-Current weaning rx (setting – mins/hrs/times per day): _____

Patient has tracheotomy Yes___ No___ If Yes, date performed: __/__/__

Responsible MD: ◻ Critical Care MD
◻ Ward Attending
◻ Other Attending MD *(specify)* _____

Responsible MD's Prognostic Estimates: *(Transcribed as percentages from tablet VAS)*
Ventilator Liberation: _____ [N/A if already liberated from ventilator] 3-Month Survival _____
One-year Survival: _____ Functional Independence: _____

Provent Score Mortality Estimate _____

予後

Responsible MD's Expectations for:
Care Needs: _____
Discharge Site: _____
Cognitive Status: _____
Functional Status: _____

Patient Treatment Preferences (per Responsible MD understanding):
Resuscitation Preference:
◻ Attempt resusc ◻ Do not attempt resusc ◻ Resusc pref unknown to ICU MD

Advance Directive re Other Treatments:
◻ No limitation ◻ Limitation, specify _____

コード

Insights/Impressions About Primary Surrogate:

Responsible MD Plans to Attend SIT-2 Meeting: ◻Yes ◻No

2回目のPre meetingの内容
担当医が考える今後のプラン

Responsible MD's Preliminary Thoughts About Appropriate Care Plan: *(Check all that apply)*

- ☐ Proceed with tracheotomy (if not already done)
- ☐ Continue (or resume if liberated) MV/intensive care therapy without limitation at this time
- ☐ Referral for placement in weaning facility
- ☐ Continue (or resume if liberated) with short (≤ 7 days) further trial of MV/intensive care, but readdress goals soon
- ☐ Exclusive focus on palliative care
- ☐ Withdraw (or withhold if liberated) life-sustaining therapy
- ☐ Uncertain / Equivocal (check only if no other box is checked)
- ☐ Other /Additional Comments _____

SITによるmeetingの内容

Main objectives of SIT Meetings

- Determine the family's understanding of the patient's illness, prognosis and treatments
- Enhance the family's understanding of chronic critical illness
- Discuss potential burdens and benefits of continuing intensive care treatment
- Explore relevant values of the patient and family
- Elicit treatment preferences that the patient may have expressed
- Align family expectations with clinicians ' expectations
- Integrate information previously received from multiple caregivers
- Discuss expected care needs for the longer term, in light of the patient's cognitive and functional status and level of dependence on medical and nursing interventions
- Contribute other information and support as needed by the family for establishing goals of care with the ICU physician

ミーティングで
話すMain項目

Supportive Information Team: Guide for Clinicians

CHRONIC CRITICAL ILLNESS: KEY POINTS

- Half of patients are liberated from the ventilator
- Complications are common- especially the infections
- Few patients with chronic critical illness ever go home
- If they do leave the hospital, often readmitted soon after (of days alive, ¾ spent in a facility)
- At least half are dead within 3-6 months of hospital discharge

慢性重症疾患
の一般論

SIT MEETING CONTENT	HELPFUL LANGUAGE
Explain SIT clinician's role: • Service you represent • Your function in the study • Assistance you can offer • Coordination with ICU clinicians	"We are here to provide a framework of information and support for decisions you may face in the hospital."
Initiate dialogue regarding patient's condition and likely outcomes	"What have the doctors told you about [PATIENT'S] condition?"
Discuss treatment options in the context of patient's values/goals/preferences	"Our job here is to help you make decisions with the ICU team in an informed way." "What is most important to [PATIENT]?" "What do you think [PATIENT] would decide?"
Plan for follow-up	"We will plan to meet again [WHEN] and are available sooner if it would be helpful."

ミーティングで話すMain項目

- 患者の病状・予後・治療についての家族の理解度を確認
- 慢性重症疾患についての理解を促す
- 集中治療を継続することの利益と害を議論する
- 患者の家族の価値観を共有する
- 患者の治療に対する考え方を引き出す
- 臨床医の期待と家族の期待をすり合わせる
- 他職種の介護者から集めた情報を前もって統合しておく
- 患者の認知機能・身体機能や医学的観点から長期的なケアについて議論する
- ICU医とともにgoal of careを作って、求められることについて議論する

慢性重症疾患の一般論

- 人工呼吸器から離脱できるのは半数程度
- 合併症として感染が約半数で起こる
- 家に帰ることができるのはほとんどいない
- 再入院率が高い
- 退院後３～６ヶ月後以内に少なくても半数が死亡する

SITによるmeeting項目

SIT Meeting Topics Covered, No. (%)	**SIT-1** (n = 112)	**SIT-2** (n = 64)
Introduction of Participants	112 (100)	64 (100)
Patient's Condition	112 (100)	64 (100)
Patient's Prognosis	112 (100)	58 (91)
Alternatives to Continued Intensive Care Therapy	52 (46)	22 (34)
Care Settings for Chronically Critically Ill Patients (SIT-1 only)	64 (57)	----
Patient Advance Directive	72 (64)	26 (41)
Likely Discharge Options (SIT-2 only)	----	47 (75)
Patient's Likely Care Needs (SIT-2 only)	----	47 (75)
Family Summarized Discussion	72 (64)	45 (70)
Family's Understanding of Patient's Values/Goals/Preferences	100 (89)	52 (81)
Plan for Follow Up with the Responsible MD	72 (64)	38 (60)
Plan for Follow Up with SIT Clinicians	88 (79)	24 (38)

Study outcome

- Primary outcome
  意思決定者の90日後のHADS score

- Secondary outcome
  意思決定者の90日後のIESスコア（PTSD 症状）
  治療のゴールに対する患者の意向
  コミュニケーションの質
  患者満足度
  患者のoutcome

HADS symptom score

不安
1 張りつめていると感じる
2 ひどいことが起こらないかと恐ろしい
3 心配事が心をめぐる
4 安心しリラックスしていると感じる
5 怖じ気づいていると感じる
6 はじめるとき落ち着きなく感じる
7 急にパニックを感じたりする

抑うつ
1 以前と同様に楽しめる
2 おもしろさがわかり笑ったりできる
3 楽しく感じる
4 怠けているような感じがする
5 自分の見栄えに興味がなくなった
6 楽しむことが待ち遠しい
7 読書やラジオ，テレビを楽しめる

7つの不安に関する質問、7つの抑うつに関する質問の、計14の質問からなる

計42点
それぞれの点数が8点以上で、不安状態、抑うつ状態と判断

Acta Psychiatr Scand. 1983;67(6):361-370.

IES-R

		Not at all	A little bit	Moderately	Quite a bit	Extemely
1	Any reminder brought back feelings about it	0	1	2	3	4
2	I had trouble staying asleep	0	1	2	3	4
3	Other things kept making me think about it	0	1	2	3	4
4	I felt irritable and angry	0	1	2	3	4
5	I avoided letting myself get upset when I thought about it or was reminded of it	0	1	2	3	4
6	I thought about it when I didn't mean to	0	1	2	3	4
7	I felt as if it hadn't happened or wasn't real	0	1	2	3	4
8	I stayed away from reminders about it	0	1	2	3	4
9	Pictures about it popped into my mind	0	1	2	3	4
10	I was jumpy and easily startled	0	1	2	3	4
11	I tried not to think about it	0	1	2	3	4

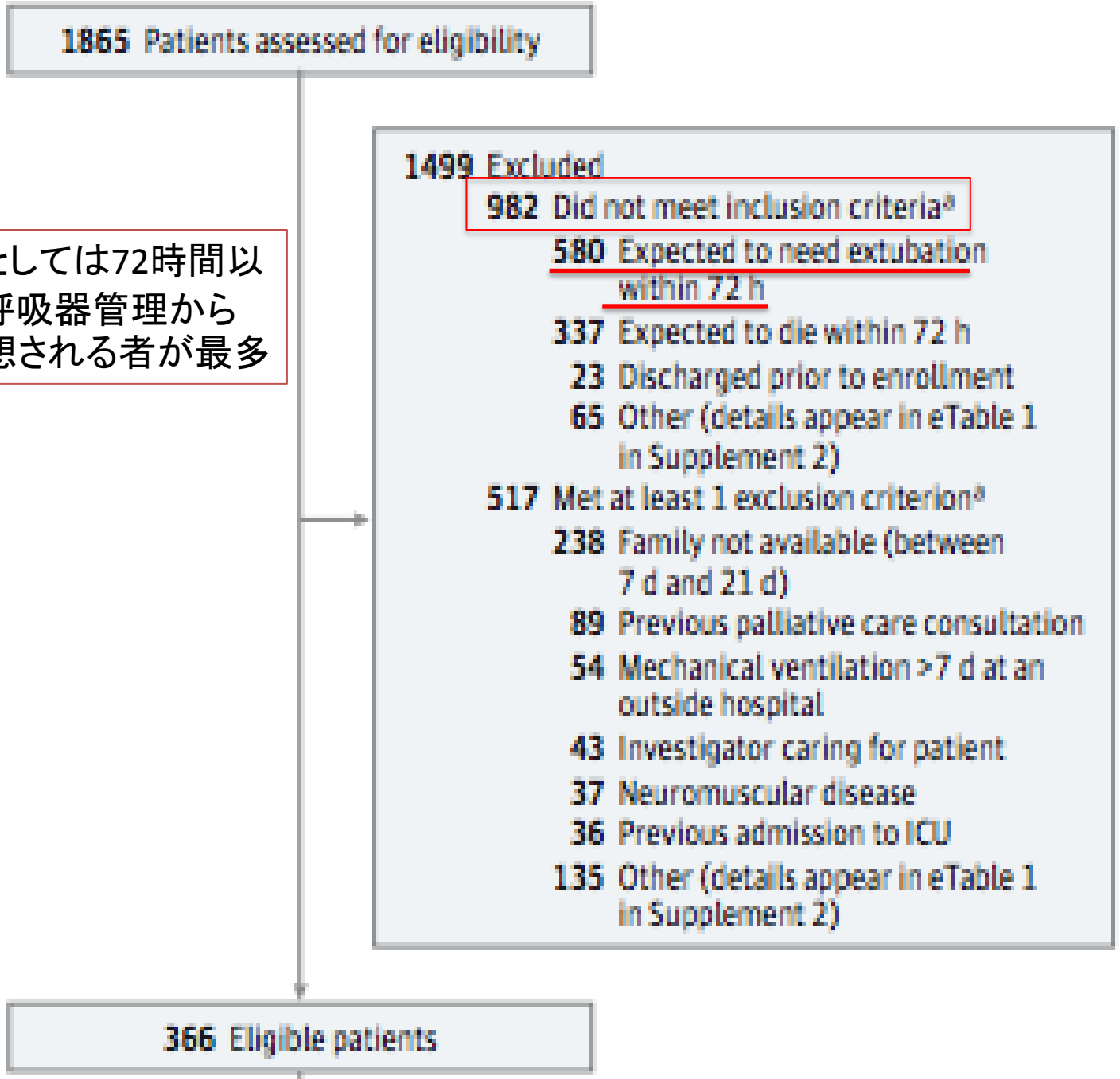
		Not at all	A little bit	Moderately	Quite a bit	Extemely
12	I was aware that I still had a lot of feelings about it, but I didn't deal with them	0	1	2	3	4
13	My feelings about it were kind of numb	0	1	2	3	4
14	I found myself acting or feeling as though I was back at that time	0	1	2	3	4
15	I had trouble falling asleep	0	1	2	3	4
16	I had waves of strong feelings about it	0	1	2	3	4
17	I tried to remove it from my memory	0	1	2	3	4
18	I had trouble concentrating	0	1	2	3	4
19	Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart	0	1	2	3	4
20	I had dreams about it	0	1	2	3	4
21	I felt watchful or on-guard	0	1	2	3	4
22	I tried not to talk about it	0	1	2	3	4

心的外傷ストレス症状を測定するための自記式質問紙
侵入症状(８項目)・回避症状（８項目）・過覚醒症状（６項目）それぞれの項目が0~4点の５項目からなる。33点/88点以上がPTSDの可能性を示唆する

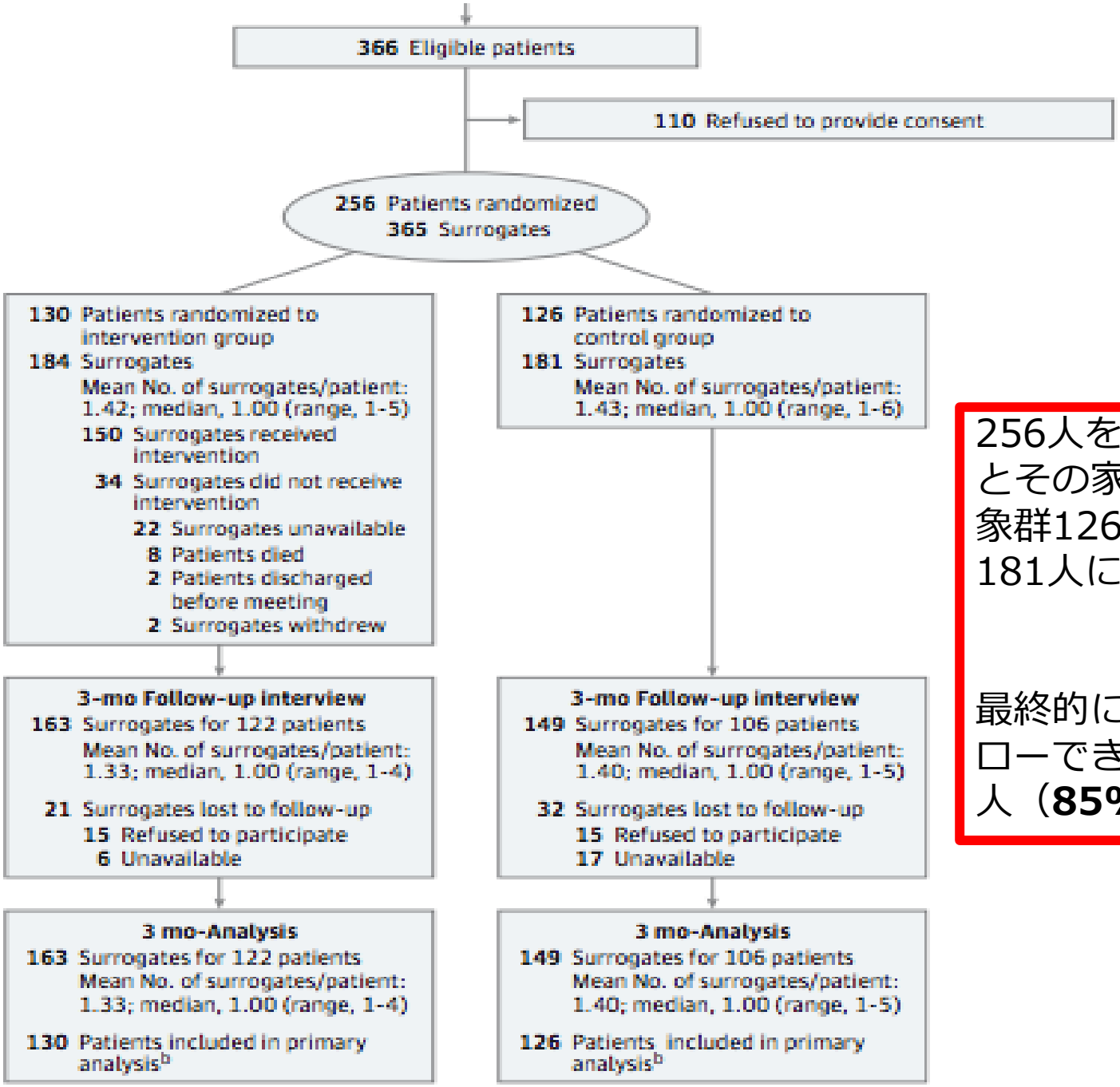
Statistical Analysis

- 先行研究より、介入群でHADSスコアの平均が1.5点低いと予測し、αエラー0.05、power 90%で、サンプルサイズを計算
- 両群それぞれ150名必要と算出
- 全ての解析はIntention-To-Treat basisで行われた

Result



除外基準としては72時間以内に人工呼吸器管理から離脱が予想される者が最多



256人を介入群130人とその家族184人、対象群126人とその家族181人にランダム割付

最終的に３ヶ月フォローできたのが計312人（**85%**）→**解析**

Characteristic	Patients[a]	
	Intervention Group (n = 130)	Control Group (n = 126)
Age, mean (95% CI), y	58 (55.2-60.8)	57 (54.0-59.7)
Female sex, No. (%)	66 (51)	65 (52)
Ethnicity, No. (%)		
Hispanic or Latino	17 (13)	15 (12)
Non-Hispanic or Non-Latino	112 (87)	111 (88)
Race, No. (%)		
Black	32 (25)	31 (25)
American Indian/Alaskan Native	1 (1)	4 (3)
Asian	6 (5)	3 (2)
White	79 (61)	79 (63)
Missing	11 (9)	9 (7)
Religion, No. (%)		
Catholic	29 (23)	22 (18)
Protestant	42 (33)	38 (30)
Jewish	8 (6)	8 (6)
Muslim	2 (2)	2 (2)
None	9 (7)	6 (5)
Other	38 (30)	51 (41)
Insurance, No. (%)		
Medicare	60 (46)	57 (45)
Medicaid	11 (8)	16 (13)
Commercial	47 (36)	36 (29)
None	9 (7)	11 (9)
Other	3 (2)	6 (5)
Study site, No. (%)		
Mount Sinai Medical Center	43 (33)	41 (33)
University of North Carolina Hospitals	43 (33)	41 (33)
Duke University Medical Center	23 (18)	23 (18)
Duke Regional Hospital	21 (16)	21 (17)

介入した患者の年齢、性別、人種、宗教などに優位な差はなし

Characteristic	Patients[a]	
	Intervention Group (n = 130)	Control Group (n = 126)
Activities of daily living score,[21] mean (95% CI)[b]	5.1 (4.8-5.4)	4.5 (4.1-4.8)
Instrumental activities of daily living score,[22] mean (95% CI)[c]	5.4 (5.0-5.9)	5.0 (4.5-5.5)
Chronic comorbidities, mean No./patient (95% CI)	2.2 (1.9-2.4)	2.2 (1.8-2.5)
Acute comorbidities, mean No./patient (95% CI)	2.3 (2.0-2.6)	2.6 (2.3-2.9)
APACHE II score at enrollment, mean (95% CI)	26.2 (25.2-27.3)	25.8 (24.6-27.0)
ProVent 14 score,[2] mean (95% CI)[d]	2.7 (2.5-3.0)	2.6 (2.4-2.8)
Predicted 1-y mortality, mean % (95% CI)	59 (54.2-63.3)	55 (50.7-60.2)
Renal replacement therapy during hospitalization, No. (%)	40 (31)	38 (30)
Vasopressors during hospitalization, No. (%)	106 (82)	99 (79)
Had advance directive at enrollment, No. (%)	14 (11)	18 (14)
Cardiopulmonary resuscitation preference at enrollment, No. (%)		
Perform it	118 (91)	115 (91)
Forego it	12 (9)	11 (9)
No. of surrogate decision makers per patient, No. (%)		
1 (primary decision maker only)	89 (68)	88 (70)
2 (primary plus 1 additional)	31 (24)	29 (23)
>2 (primary plus multiple additional ones)	10 (8)	9 (7)

介入群の方が優位に日常生活が自立していた

Characteristic	Surrogate Decision Makers[a]	
	Intervention Group (n = 184)	Control Group (n = 181)
Age, mean (95% CI), y	51 (48.8-52.8)	51 (48.6-52.7)
Female sex, No. (%)	128 (70)	131 (72)
Ethnicity, No. (%)		
Hispanic or Latino	28 (15)	23 (13)
Non-Hispanic or Non-Latino	155 (85)	158 (87)
Marital status, No. (%)		
Married	108 (59)	120 (66)
Separated	10 (5)	7 (4)
Divorced	15 (8)	16 (9)
Widowed	33 (18)	29 (16)
Single	11 (6)	4 (2)
Missing	7 (4)	5 (3)
Primary surrogate's relationship to patient, No. (%)		
Child (age >18 y)	41 (32)	41 (33)
Parent	18 (14)	17 (13)
Sibling	11 (8)	15 (12)
Spouse or partner	57 (44)	47 (37)
Other	3 (2)	6 (5)

意思決定者も年齢、性別に大きな差はなし
意思決定者は子供が41%と最多

Characteristic	Surrogate Decision Makers[a]	
	Intervention Group (n = 184)	Control Group (n = 181)
Employed	103 (57)	93 (51)
Unemployed (not disabled)	15 (8)	22 (12)
Homemaker	10 (6)	16 (9)
Retired	40 (22)	25 (14)
Disabled	13 (7)	22 (12)
Student	1 (1)	3 (2)
Treated for anxiety in the past, No. (%)	38 (21)	45 (25)
Treated for depression in the past, No. (%)	54 (29)	53 (29)
No. of surrogate decision makers by study site		
Mount Sinai Medical Center	62 (34)	53 (29)
University of North Carolina Hospitals	58 (32)	57 (32)
Duke University Medical Center	30 (16)	37 (20)
Duke Regional Hospital	34 (18)	34 (19)
Hospital Anxiety and Depression Scale unadjusted score at baseline, mean (SD)		
Total[b]	16.0 (8.1)	16.4 (8.4)
Anxiety subscale[c]	9.5 (4.8)	9.8 (4.7)

過去に不安や抑うつ症状での治療歴にも差はなし

Primary Outcome

	Surrogate Decision Makers		Difference Between Groups, Mean (95% CI)	*P* Value
	Intervention Group	Control Group		
Hospital Anxiety and Depression Scale (HADS) Score at 3 mo[a]				
No. of surrogate decision makers	163	149		
Total unadjusted, mean (SD)	12.1 (8.0)	11.4 (8.6)		
Adjusted, mean (95% CI)				
Baseline and multiple respondents	12.2 (11.0 to 13.4)	11.4 (10.1 to 12.6)	0.8 (−0.9 to 2.6)	.34
Baseline, multiple respondents, and study site	12.2 (11.0 to 13.4)	11.4 (10.2 to 12.6)	0.8 (−1.0 to 2.5)	.38
Baseline, multiple respondents, study site, race, sex, and primary or additional surrogate	11.8 (10.4 to 13.2)	11.1 (9.7 to 12.5)	0.7 (−1.0 to 2.5)	.41
Baseline, multiple respondents, study site, race, sex, primary or additional surrogate, and patient death by time of interview	12.0 (10.6 to 13.4)	11.4 (10.0 to 12.8)	0.7 (−1.1 to 2.4)	.45

平均のHADS scoreに両群間で優位差なし

	Surrogate Decision Makers		Difference Between Groups, Mean (95% CI)	*P* Value
	Intervention Group	Control Group		
HADS Anxiety Subscale Score at 3 mo[b]				
No. of surrogate decision makers	163	149		
Total unadjusted, mean (SD)	7.2 (4.6)	6.4 (4.7)		
Adjusted, mean (95% CI)				
Baseline and multiple respondents	7.2 (6.6 to 7.9)	6.4 (5.7 to 7.1)	0.8 (−0.1 to 1.8)	.09
Baseline, multiple respondents, and study site	7.2 (6.5 to 7.9)	6.4 (5.7 to 7.1)	0.8 (−0.2 to 1.8)	.11
Baseline, multiple respondents, study site, race, sex, and primary or additional surrogate	7.3 (6.5 to 8.1)	6.5 (5.7 to 7.3)	0.8 (−0.2 to 1.8)	.12
Consistent with anxiety (score ≥8), adjusted for baseline and multiple respondents, % (95% CI)	44 (35 to 53)	31 (23 to 40)	1.72 (1.00 to 3.00)[c]	.05
HADS Depression Subscale Score at 3 mo[b]				
No. of surrogate decision makers	163	149		
Total unadjusted, mean (SD)	4.9 (4.2)	5.0 (4.5)		
Adjusted, mean (95% CI)				
Baseline and multiple respondents	5.0 (4.4 to 5.6)	5.0 (4.3 to 5.6)	0 (−0.9 to 0.9)	.93
Baseline, multiple respondents, and study site	5.0 (4.4 to 5.6)	5.0 (4.3 to 5.7)	0 (−0.9 to 0.9)	.96
Baseline, multiple respondents, study site, race, sex, and primary or additional surrogate	4.6 (3.9 to 5.3)	4.6 (3.8 to 5.4)	0 (−0.9 to 0.9)	.97
Consistent with depression (score ≥8), adjusted for baseline and multiple respondents, % (95% CI)	24 (17 to 31)	22 (16 to 30)	1.09 (0.62 to 1.92)[c]	.77

不安症状、抑うつ症状に分けても、両群間で有意差なし
いずれも8点以下であった

Secondary Outcome

	Surrogate Decision Makers		Difference Between Groups, Mean (95% CI)	*P* Value
	Intervention Group	Control Group		
Impact of Events Scale-Revised (IES-R) Score at 3 mo[d]				
No. of surrogate decision makers	161	145		
Total unadjusted, mean (SD)	25.6 (18.0)	20.7 (18.3)		
Adjusted, mean (95% CI)				
Multiple respondents	25.9 (22.8 to 29.0)	21.3 (18.0 to 24.6)	4.60 (0.01 to 9.10)	.0495
Multiple respondents and study site	25.5 (22.7 to 29.0)	21.3 (17.9 to 24.7)	4.5 (0 to 9.0)	.05
Multiple respondents, study site, race, sex, and primary or additional surrogate	24.2 (20.6 to 27.8)	19.9 (16.1 to 23.7)	4.3 (−0.2 to 8.9)	.06
Multiple respondents, study site, race, sex, primary or additional surrogate, and patient death by time of interview	25.3 (21.7 to 28.9)	21.3 (17.5 to 25.1)	4.1 (−0.3 to 8.5)	.06
Consistent with PTSD (score >33), adjusted for multiple respondents, % (95% CI)	34 (27 to 42)	25 (18 to 33)	1.56 (0.90 to 2.60)[c]	.10
IES-R Avoidance Subscale Score at 3 mo[e]				
No. of surrogate decision makers	161	145		
Total unadjusted, mean (SD)	8.8 (7.1)	7.1 (6.9)		
Adjusted, mean (95% CI)				
Multiple respondents	8.8 (7.7 to 10.0)	7.1 (5.9 to 8.4)	1.70 (0.02 to 3.30)	.048
Multiple respondents and study site	8.8 (7.7 to 9.9)	7.1 (5.9 to 8.3)	1.6 (0 to 3.3)	.06
Multiple respondents, study site, race, sex, and primary or additional surrogate	8.5 (7.2 to 9.8)	6.9 (5.6 to 8.2)	1.5 (−0.1 to 3.2)	.07

IES—Rは介入群で有意に高値
特に回避・過覚醒については介入群の方が有意に発症率が高値

	Surrogate Decision Makers		Difference Between Groups, Mean (95% CI)	*P* Value
	Intervention Group	Control Group		
IES-R Hyperarousal Subscale Score at 3 mo[e]				
No. of surrogate decision makers	161	145		
Total unadjusted, mean (SD)	5.9 (5.3)	4.3 (5.0)		
Adjusted, mean (95% CI)				
Multiple respondents	5.9 (5.0 to 6.8)	4.4 (3.4 to 5.4)	1.5 (0.1 to 2.8)	.03
Multiple respondents and study site	5.8 (5.0 to 6.8)	4.4 (3.4 to 5.4)	1.5 (0.1 to 2.8)	.03
Multiple respondents, study site, race, sex, and primary or additional surrogate	5.4 (4.4 to 6.4)	4.0 (2.9 to 5.1)	1.4 (0.1 to 2.8)	.04
IES-R Intrusion Subscale Score at 3 mo[f]				
No. of surrogate decision makers	161	145		
Total unadjusted, mean (SD)	11.0 (7.9)	9.4 (8.2)		
Adjusted, mean (95% CI)				
Multiple respondents	11.1 (9.7 to 12.4)	9.7 (8.2 to 11.1)	1.4 (−0.6 to 3.4)	.17
Multiple respondents and study site	11.1 (9.8 to 12.4)	9.7 (8.3 to 11.1)	1.4 (−0.6 to 3.4)	.17
Multiple respondents, study site, race, sex, and primary or additional surrogate	10.0 (8.4 to 11.6)	8.8 (7.2 to 10.4)	1.3 (−0.7 to 3.3)	.21

特に回避・過覚醒については介入群の方が有意に発症率が高値
侵入に関しては両群で有意差なし

	Intervention Group	Control Group	Odds Ratio (95% CI)	*P* Value
After-Death Bereaved Family Interview				
Encourage Advance Care Planning Dimension				
Answered "yes" to all 3 patient preference measures, % (95% CI)[d]	75 (67 to 82)	83 (75 to 89)	0.63 (0.34 to 1.16)	.14
Answered "yes" to "Did physician discuss patient wishes about medical treatment?," No. (%)	144 (95)	131 (94)		
Answered "yes" to "Did physician discuss if care was consistent with patient wishes?," No. (%)	136 (90)	133 (96)		
Answered "yes" to "Were all medical procedures and treatments consistent with patient wishes?," No. (%)	135 (89)	128 (92)		
Dimension Score, mean (95% CI)[a,b]			Difference Between Groups (95% CI)	
Physical comfort and emotional support	0.14 (0.10 to 0.18)	0.11 (0.07 to 0.15)	0.02 (−0.02 to 0.07)	.32
Inform and promote shared decision making	0.18 (0.14 to 0.22)	0.15 (0.11 to 0.19)	0.04 (−0.02 to 0.09)	.22
Encourage advance care planning	0.16 (0.10 to 0.22)	0.13 (0.07 to 0.19)	0.04 (−0.04 to 0.10)	.39
Focus on individual	0.20 (0.16 to 0.24)	0.16 (0.12 to 0.20)	0.04 (−0.02 to 0.10)	.21
Attend to emotional and spiritual needs of the family	0.14 (0.10 to 0.18)	0.11 (0.07 to 0.15)	0.02 (−0.02 to 0.07)	.32
Overall[c]	8.80 (8.54 to 9.06)	8.99 (8.71 to 9.27)	−0.19 (−0.57 to 0.19)	.33
24-item Family Satisfaction in the Intensive Care Unit Survey Score, mean (95% CI)[a,d]				
Satisfaction with care subscale	81.2 (78.2 to 84.2)	84.0 (80.8 to 87.2)	−2.8 (−7.1 to 1.4)	.19
Satisfaction with decision-making subscale	80.9 (77.9 to 83.9)	84.6 (81.2 to 88.0)	−3.6 (−8.1 to 0.9)	.11
Total score	81.1 (78.3 to 83.9)	84.3 (81.3 to 87.3)	−3.1 (−7.3 to 1.0)	.13

患者の意向の反映度には両群で有意差はなし
患者満足度は両群で有意差はなし

Outcome	Median (Interquartile Range) Intervention Group (n = 130)	Control Group (n = 126)	Difference BetweenGroups (95% CI)	P Value
Total ventilator days	19 (15 to 31)	21 (14 to 35)	−2 (−4 to 2)	.59
After randomization	10 (5 to 20)	12 (5 to 27)	−2 (−3 to 1)	.42
Total ICU days	19 (15 to 26)	20 (15 to 30)	−1 (−3 to 1)	.51
After randomization	9 (6 to 15)	10 (5 to 17)	−1 (−2 to 1)	.72
Total hospital days	35 (23 to 52)	36 (23 to 54)	−1 (−6 to 4)	.78
For deceased patients[a]	25 (18 to 36)	24 (14 to 39)	1 (−7 to 4)	.60
After randomization	19 (12 to 37)	23 (12 to 39)	−4 (−6 to 3)	.51
	No. (%)		Odds Ratio (95% CI)	
Hospital mortality	49 (38)	51 (40)	0.89 (0.53 to 1.47)	.65
Limitations of ICU treatment				
Mechanical ventilation	40 (31)	33 (26)	1.3 (0.7 to 2.2)	.41
Dialysis	13 (10)	15 (12)	0.8 (0.4 to 1.8)	.64
Nutrition	18 (14)	21 (17)	0.8 (0.4 to 1.6)	.60
Vasopressors	18 (14)	19 (15)	0.9 (0.4 to 1.8)	.86
Hospital discharge disposition[b]				
Home	15 (19)	18 (24)		.62
Home with paid assistance	10 (12)	7 (9)		
Hospice	3 (4)	4 (5)		
Acute rehabilitation facility	22 (27)	15 (20)		
Long-term acute care hospital	12 (15)	12 (16)		
Other acute care facility	0	1 (1)		
Skilled nursing facility	19 (23)	16 (21)		
Other	0	2 (3)		

人工呼吸器期間・ICU日数・入院日数・死亡率に両群で有意差なし

Summary of result

- 緩和ケア医のprotocolにもとずいた情報提供や感情のサポートは、３ヶ月後の意思決定者の不安やうつ症状減らすことはできなかった
- むしろPTSDの発症を増やした
- 患者の生存期間・入院期間・人工呼吸器期間にも影響は及ぼさない

Limitation

- SIT群も平均して1.9回ICU医単独によるミーティングが行われている
- open labelである

Discussion

- 個々の医師のコミュニケーションの質や普段の患者管理の満足度も影響している
- 初期に病状について説明した後すぐに、今後の展開に関して話をすることは、家族を動揺させることにつながる
- 慢性重症疾患のケアをprotocolにそった２回のミーティングでケアするというのはそもそも不十分だった
- 緩和治療医師にprotocolにそってサポートさせることは彼らがいつもしているやり方とは違う
- 介入が制限されていたことが結果に影響を及ぼした可能性はある

Conclusion

- 長期化した重症患者への緩和治療医師による家族とのミーティングは不安やうつを減らすわけではなく、PTSD症状を増やす可能性がある

- 本研究より、長期化した重症患者に対して、緩和治療医師の介入をルーチーンにすることは推奨されない

当院での見解

- そもそもPICS及びPICS-Fに対する意識が低いように思われる

- ABCDEFGHバンドル、特にFGHバンドルについてできることはないか？
- 家族への関わり方、フォローを見直す
- ICUから退出する際の引き継ぎで、家族のことももれなく行う
- PICS、PICS-Fについて啓蒙する（スタッフも含め、パンフレット・ICUダイアリーなど）

PAD guidelineでは

- PICS-F予防のためにICUにおいて整えるべき環境

①面会をフレキシブルに行い、「患者のそばにいたい」という家族の要望に応える

②家族にベッドサイドに来てもらい、患者のケアに参加してもらうことでゴールについてイメージしてもらう

③意思決定に関わる十分な情報を提供し、家族の考えを知って、医療者と家族の感覚のズレを少なくする

Crit Care Med 2013; 41:S136–S145