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Advance care planning for the severely ill in the hospital: a randomized trial

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ABSTRACT

Objectives To investigate the impact of advance care planning (ACP) including decision aids for severely ill medical inpatients.

Methods Single-centre randomised controlled trial at a Swiss university hospital. Patients were randomly assigned (1:1) to receive an extra consultation with the hospital social service or a consultation with in-house facilitators trained according to an internationally established ACP programme. Trial participants with the exception of the observers were fully blinded. 115 competent severely ill adults, their surrogates and their attending physicians were enrolled and followed for 6 months after discharge or 3 months after death. The patient's wishes regarding resuscitation (primary outcome), last place of care and other end-of-life wishes were recorded. Knowledge and respect of the patient's wishes by the surrogates and attending physician were monitored.

Results Compared with controls, 6 months after the intervention, fewer patients wished to be resuscitated or were undecided (p=0.01), resuscitation wishes were documented more frequently (89% vs 64%, p=0.02) and surrogates and/or attending physicians had greater knowledge of the patient's wishes (62% vs 30%, p=0.01). Groups were not different with regard to wishes being fulfilled, with the exception of last place of care being achieved more frequently in the intervention group (29% vs 11 %, p=0.05).

Conclusion ACP including decision aids offered to severely ill medical inpatients leads to greater knowledge, documentation and respect of treatment and end-of-life wishes. Introducing ACP to these patients however may be too late for many patients. Early integration of ACP during the illness trajectory and a broader regional approach may be more appropriate.

INTRODUCTION

Advance care planning (ACP) has attracted growing attention since the 1990s. ACP describes a structured interactive process involving patients, their loved ones and their care providers to plan future treatments that respect patients' wishes and goals.[1 2] Over the past 20 years the focus has shifted from completion of advance directives to effective professional communication promoting patient-centred goals-of-care discussions for future care. Several systematic reviews on the effectiveness of ACP strategies[3–5] indicate that ACP interventions increase the number of advance directives (ADs) and do-not-attempt-to-resuscitate orders (DNAR). More complex ACP interventions improve the quality of end-of-life care and the concordance of patients' preferences with care.[6] Some studies, mostly of low quality,[7] include encouraging patients to complete ADs or placing DNAR orders without professional communication such as ACP, which is contrary to the core definition of the concept.[1 2] An additional form of ACP interventions focuses on delivery of information through evidence-based decision aids without offering professional ACP communication. Systematic reviews on ACP decision aids for future care[3 8–10] suggest that patients have less decisional conflict and tend to favour less intensive care similar to the impact of decision aids for current treatment decisions,[11] although studies in the palliative care context are still rare.[12] In none of the complex interventions were the two concepts of ACP facilitation and ACP decision aids combined. However, both concepts are necessary for delivering patient-centred care and improving evidence-based patient choice for future treatments. Although experts in the

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field consider care consistent with goals as the most important outcome measure of ACP,[13] this has not often been objectively measured. Most commonly this is inferred by asking surrogates if patients' wishes were fulfilled, using proxies such as combined measures of wishes known and fulfilled, or reviewing documentation in medical charts as wish fulfilment without reporting how the patients' wishes were evaluated[6]. ACP experts described this discrepancy as 'a dilemma for our field of research, and potentially setting up a policy dilemma as well'[13](page 7).

We report the outcomes of a patient, surrogate and physician-blinded parallel group randomised controlled trial on the impact of ACP on knowledge and fulfilment of concrete treatment wishes among severely ill adult medical inpatients. The ACP intervention was delivered by in-house non-physician ACP facilitators, who underwent a 2-day communication skills training in 2013 before study start (see online supplementary file 1) based on the Australian Respecting Patient Choices and the German beizeiten begleiten programmes. Both of these programmes are rooted in the US-American Respecting Choices initiative. Different from former programmes, the use of evidence-based ACP decision aids was included in the training and process. In 2010, only about 10% of the population >75 years had ADs in a Swiss national survey in 2010.[14] In 2013, a national law declared AD as binding.[15] Before our study began, there was no Swiss ACP programme in place. Our complex intervention was therefore introduced in an 'ACP-naïve' context such that a randomised controlled trial including blinding of patient and caregiver and concealment of allocation was possible. Our study (Multidisciplinary advance care planning and shared decision-making for end-of-life care trial, MAPS trial) is part of a national research programme on end-of-life care (NFP 67 end-of-life care). All data are open to be shared.

METHODS

Study design

The study team screened all patients once weekly on seven inpatient units participating in the study. Randomisation into intervention and control group was performed (1:1) by the clinical trial centre using a static unstratified multiblock computer randomisation to maintain balance across the seven units. The attending physician (general practitioner or specialist) in charge after discharge and the potential surrogate decision-makers of enrolled patients were also invited to participate. To blind patients and their surrogates, they were asked to participate in a study testing the impact of two different communication tools on discharge planning for severely ill patients on their quality of care received after discharge, without being informed of what to expect in each tool. Participating attending physicians were also blinded to the intervention by using the same information. Twelve patient surrogates declined to consent for the study and two patients withdrew shortly after randomisation. No further data were obtained for these 14 patient surrogate dyads after baseline assessment, but they were included into the analysis by multiple imputation (see below). Interviews after the interventions were conducted in both groups face-to-face or by telephone. Medical records were reviewed 6 months after discharge/intervention. Due to limited study resources, observers were not fully blinded since they screened patients for inclusion and interviewed patients after the interventions. Data monitoring and analysis were undertaken by blinded study team members on an intention-to-treat basis. In total, 115 patients were recruited between July 30 2013 and December 18 2014 to ensure a maximum follow-up of 9 months. Follow-up was completed in August 2015. Many patients were treated or died outside of the study hospital requiring further data collection, which was completed by September 2016.

Study participants

Eligible patients were ≥age 18 admitted to internal medicine, oncology, radiation oncology, haematology, nephrology, dermatology or neurology wards at the University Hospital of Zurich. All patients were competent as assessed by their attending physicians and had sufficient German-language skills to follow the study procedures. Physicians assessed patients using a screening tool for palliative care needs, including the 12 months surprise question.[16] All patients with a positive 12 months surprise question (ie, 'I would not be surprised if my patient dies within the next 12 months') were approached and invited to participate. The eligibility criteria were revised during the trial to permit inclusion of severely ill patients admitted to acute day wards of the hospital units and who were discharged within 2 days, if regular ambulatory follow-up was planned.

Intervention

Patients randomised to the intervention group received ACP counselling from one of seven in-house ACP facilitators (ie, two social workers, one chaplain, two palliative care nurses and two patient counsellors, trained in ACP as summarised in online supplementary file 1) either during their hospital stay or during their next regular ambulatory visit(s). Patients randomised to the control group received counselling sessions by hospital social workers who had no training in ACP. The control group conversation addressed special needs of patients as identified by the patients themselves. The ACP facilitators offered a person-centred goals-of-care discussion to patients and their surrogates, according to the Respecting Patient Choices and beizeiten begleiten guidance, regarding their wishes in cases of future emergencies, possible incapacity for decision-making and deterioration of health status. Facilitators delivered up to three conversations, each

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lasting between 60 and 90 min. In addition, a 9 min video decision aid combining descriptions on general goals of care and cardiopulmonary resuscitation[17 18] and a written decision aid library addressing resuscitation, intubation, dialysis, tube feeding and last place of care (in German only, available on request), based on previously published ones were offered during the consultation if desired.[19–26] All decision aids except two[25 26] had been included in the abovementioned systematic reviews on ACP decision aids, and all are registered in the Ottawa decision aid inventory.[27] Patients' wishes regarding their goals of care were documented in an AD if desired, which included an emergency form, developed by the beizeiten begleiten programme, adapted for Switzerland (in German only, available on request).

Study assessment

Baseline data including socio-demographics, basic ACP-relevant information and criteria for palliative needs assessments as recommended[16] were collected in all screened patients to assess possible differences between patients who were or were not included in the study. ACP-relevant questions were also posed to patients who did not want to participate in the study in a short questionnaire. The first assessment of the impact of the intervention was conducted face-to-face in the hospital directly after the ACP or the control group conversation, or by telephone after discharge. For patients enrolled on acute day wards, who received the ACP or control group conversations during their next ambulatory visits, initial data on the impact of the interventions were obtained after the conversations and endpoints were assessed 6 months after the interventions. In order to avoid contamination threats (ie, asking the patient about concrete end-of-life wishes before outcome assessment, which could trigger ACP conversations in the control group) and to capture the most recent preferences of patients close to death, patients' concrete treatment wishes (ie, resuscitation, intubation, tube feeding, sedation, dialysis, intravenous fluids, antibiotics and last place of care) were assessed 6 months after discharge/intervention or after death. We independently interviewed patients, their surrogate decision-makers and attending physicians 6 months after discharge or intervention about current patients' preferences regarding each of the eight measures mentioned above. In case of death, surrogates were interviewed after 3 months to assess congruency between surrogates and physicians regarding the patient's presumed wishes, and if these were fulfilled. We constructed a tool to measure all possible categories of patients' wishes and their fulfilment. Congruency and wish fulfilment were determined by comparing the patient wishes to the surrogate and physician responses and to the medical charts. All possible cases were captured (ie, the patients had clear wishes, preferred to leave the decision to surrogate or physician, were undecided or were unable to express their wishes to the study team due to severe illness 6 months after discharge or because they died before the follow-up interview). The process of assessment of congruency between patients, surrogates and physicians is outlined in table 1. Table 2 describes the assessment of end-of-life wish fulfilment through patient, surrogate and physician interviews and by chart review for documentation and fulfilment of concrete end-of-life wishes. As inconsistencies were possible between patient, surrogate and physician statements, and documented medical outcomes, we ranked data in terms of hierarchy with regard to achievement of wish fulfilment. The column succession from left to right in table 2 illustrates the hierarchy, according to which the wish fulfilment was determined in cases of incongruences from various data sources. Medical records were reviewed during and after follow-up. Data on mortality and wish fulfilment were documented until September 2016.

Decisional conflict for future emergencies in both surrogates and patients was measured using the Decisional Conflict Scale (box 1).[28]

Depression and anxiety were measured using the Hospital Anxiety and Depression Scale (HADS)[29] at 6 months after discharge or intervention. Hospitalisation rates and last place of care were documented. We assessed the impact of death on surrogates by the impact of event scale[30] and the HADS[29] 3 months after death. Differences between decisions taken, wish fulfilment and patient outcomes were analysed between the intervention and control groups.

Power calculation

Our power calculation is based on the Australian study[6] using the primary outcome measures of wishes known to and, if applicable, respected by caregivers and as documented in medical records. As we defined wishes known by asking patients, surrogates and responsible physicians on concrete end-of-life wishes, monitored their fulfilment in the medical charts (see tables 1 and 2), and did not only use chart review regarding fulfilment of general goals of care wishes,[6] we estimated a lower baseline (10% wishes known and respected) and smaller effect (30% wishes known and respected) for the MAPS study. To achieve 90% power with a certainty of 95% for the primary outcome measure of wishes of resuscitation being known and respected, we calculated a sample size of 89 patients in each study arm, for a total of 178 patients.

Statistical analysis

Statistical analysis was performed according to Consolidated Standards of Reporting Trials (see online supplementary files 2; 3) using the intention-to-treat

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Table 1 Triple congruency measure of patients' wishes (eg, do you/does the patient want to be resuscitated?)

Patient	Surrogate	Physician	Congruency
Yes	Yes	Yes	Yes
No	No	No	Yes
Yes	Yes	Missing	Yes
No	No	Missing	Yes
Yes	Missing	Yes	Yes
No	Missing	No	Yes
Missing	Yes	Yes	Yes
Missing	No	No	Yes
Leave decision	Leave decision	Leave decision	Yes
Leave decision	Leave decision	Missing	Yes
Missing	Leave decision	Leave decision	Yes
Leave decision	Missing	Leave decision	Yes
Yes	No	Yes	No
Yes	No	No	No
No	Yes	Yes	No
No	No	Yes	No
No	Yes	No	No
Yes	No	Missing	No
No	Yes	Missing	No
Yes	Missing	No	No
No	Missing	Yes	No
Missing	Yes	No	No
Missing	No	Yes	No
Not decided	Not decided/don't know	Not decided/don't know	No
Not decided	Not decided/don't know	Missing	No
Not decided	Missing	Not decided/don't know	No
Missing	Not decided/don't know	Not decided/don't know	No
Yes/no/leave decision/not decided/don't know	Missing	Missing	Missing
Missing	Yes/no/leave decision/not decided/don't know	Missing	Missing
Missing	Missing	Yes/no/leave decision/not decided/don't know	Missing

Yes: patient agrees to (or surrogate or treating physician reports that the patient wants to) be resuscitated or intubated or dialysed, or tube fed or getting antibiotics or intravenous fluids or being sedated. Participants were also asked for their preferred last place of care.

No: patient refuses to (or surrogate or treating physician reports that the patient refuses to) be resuscitated or intubated or dialysed or tube fed or getting antibiotics or intravenous fluids or being sedated.

Leave decision: patients (or surrogate or treating physician reports that the patient wants to) leave the decision to the surrogate or the physician.

Not decided/don't know: patients do not (or surrogate or treating physician reports that the patient did not) decide or do not know what to decide.

Last place of care: patient expressed 'preferred last place of care' (home, hospice/nursing home, hospital, intensive care unit), knowledge of surrogate and physician of patient's preferred last place of care.

analysis strategy. Data were analysed at last available follow-up. Patients/surrogates who withdrew informed consent (n=14) after randomisation and from whom no data were obtained during follow-up were also included in the analysis according to intention-to-treat. ORs were calculated using logistic regression or Bayesian logistic regression. Primary outcomes were merged into one single variable to assess congruency (as described in tables 1 and 2). Given the intention-to-treat strategy, we applied two methods to deal with missing values. First, for the decisional conflict and HADS scales, an individual mean imputation was performed.[31] Second, multiple imputation was used for all other outcomes including participants who withdrew their consent after baseline assessment.[32] The two treatment groups were separately imputed and later merged into one data file for the analysis. Multiple imputation was performed with SPSS V.22, while multiple imputation pooling and outcome analysis was performed with R V.3.2.3 (for statistical methods including dual congruency seeonline supplementary file 2). According to our study design, we did not perform a posteriori tests and p value adjustment for multiple testing.[33]

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Table 2 Codes on wish fulfilment dependent on patients' wishes, the clinical situation and data on wish fulfilment by different information sources

Patients' wish	Was the patient in the situation?	Wish fulfilment (as stated by the patient)	Wish fulfilment (as stated by the surrogate)	Wish fulfilment (medical records)	Wish fulfilment (as stated by the physician)	Wish actually fulfilled?
Yes/no/don't know/leave decision	No	–	–	–	–	Not applicable
Yes/no	Yes	Yes	–	–	–	Yes
Yes/no	Yes	Missing	Yes	–	–	Yes
Yes/no	Yes	Missing	Missing	Yes	–	Yes
Yes/no	Yes	Mising	Missing	Missing	Yes	Yes
Missing	Yes	Missing	Yes	–	–	Yes
Missing	Yes	Missing	Missing	Yes	–	Yes
Missing	Yes	Missing	Missing	Missing	Yes	Yes
Leave decision	Yes	–	Yes	–	–	Yes
Leave decision	Yes	–	Missing	–	Yes	Yes
Yes/no	Yes	No	–	–	–	No
Yes/no	Yes	Missing	No	–	–	No
Yes/no	Yes	Missing	Missing	No	–	No
Yes/no	Yes	Missing	Missing	Missing	No	No
Missing	Yes	Missing	No	–	-–	No
Missing	Yes	Missing	Missing	No	–	No
Missing	Yes	Missing	Missing	Missing	No	No
Leave decision	Yes	–	No	–	–	No
Leave decision	Yes	–	Missing	–	No	No
Leave decision	Yes	–	Missing	Yes	Missing	Unclear
Leave decision	Yes	–	Missing	No	Missing	Unclear
Don't know	Yes	–	–	–	–	Unclear

Patients' wish (yes/no): patients' wish to be either resuscitated or intubated or dialysed, or tube fed or getting antibiotics or intravenous fluids or being sedated. The patient could also answer 'I don't know' or 'I leave the decision to surrogate or physician'.

Was the patient in the situation: determines whether the patient was resuscitated or intubated or dialysed, or tube fed or getting antibiotics or intravenous fluids or being sedated. If the patient was never in the situation, the wish fulfilment was recorded as not applicable.

Wish fulfilment (as stated by the patient): the documented wish fulfilment as stated by the patients had the highest priority for determining whether their wishes were fulfilled.

Wish fulfilment (as stated by the surrogate): if the wish of the patient was missing or if the patient left the decision to the surrogate, the statement of the surrogate had the highest priority for determining the patient's wish fulfilment.

Wish fulfilment (medical records): if the patient's and surrogate's wish documentation was missing, the wish fulfilment was determined according to what was stated in the medical records. This could only be determined if the patient was in the situation and if the documentation was available.

Wish fulfilment (as stated by the physician): the wish fulfilment of the patient was determined according to the statement of the physician only in the situation where the wish was not stated by the patient or surrogate, and was not documented in the medical records. However, if the patient left the decision to the surrogate or physician, and the surrogate's decision was missing, the physician's statement had priority over what was documented in the medical records.

The wish regarding last place of care: this wish was determined only if the patient was dead at the moment when wish fulfilment was assessed.

The '–' means that the statement was considered irrelevant to the determination of wish fulfilment.

RESULTS

Of 1464 patients with a positive surprise question, 946 did not fulfil all inclusion criteria (figure 1).

Most non-participation was triggered by surrogates rather than patients, mostly due to acute stress precluding additional study procedures. Eighty-eight non-participant patients agreed to answer a short questionnaire. Primary criteria of possible unmet palliative care needs[16] were assessed in 30 patients who declined to participate (non-participants) and 449 patients who were excluded (table 3). Compared with included patients, excluded patients had more complex care requirements and general decline in function, whereas participants had more acute difficult-to-control symptoms. Non-participants already had more established end-of-life wishes compared with participants (table 3). Participants were significantly younger and included more males and their (mostly) female surrogates. Patient ages ranged from 19 to 94 years (table 4). Although we screened oncology and non-oncology internal medicine wards, most patients had a primary diagnosis of cancer. We attempted to obtain follow-up data in all patients who did not withdraw informed consent, yet many missing values remained due to difficulties of reaching either patients, surrogates or responsible

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Box 1 Features of the Decisional Conflict Scale

Part A
⇒ Definition of index decision and options by research team.

Part B
⇒ Decisional Conflict Scale-16 items, 5 factors (informed, values clarity, support, uncertainty, effective decision-making).

Scores (0–100)
⇒ 0<25=low decisional conflict.
⇒ 25–37.5=moderate decisional conflict.
⇒ 37.5=high decisional conflict.

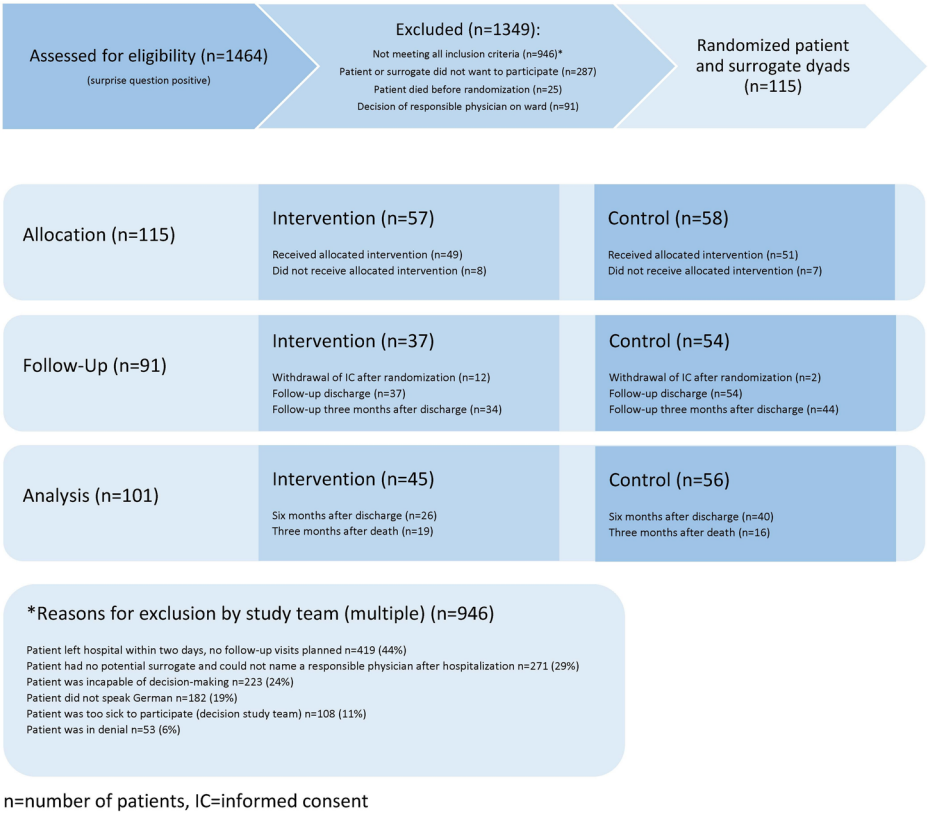
The user manual is available for free download in English.[42]

physicians in the ambulatory setting or obtaining medical records of outpatients.

Primary outcome measure: end-of-life wishes known, documented and fulfilled

We report valid percentages and multiple imputation p values for the primary outcomes of resuscitation wish and last place of care in the article (table 5). Data on other end-of-life wishes and multiple imputation data are included in online supplementary file 2.

Six months after discharge or intervention, most concrete medical end-of-life wishes including last place of care were significantly better known to surrogates and attending physicians (triad congruency) compared with the control group. All wishes (with the exception of intravenous fluids) were more often correctly documented in medical records of patients who had received the ACP intervention compared with controls (see data on CIs and p values in online supplementary file 2). ACP significantly influenced the main outcome. At baseline, most patients in both groups wanted to be resuscitated, and a high proportion of patients wanted to link their resuscitation decisions to the likely outcome of resuscitation of which they were not aware (table 4). Six months after discharge or intervention, among patients who were able to participate in a follow-up interview, no intervention patient was undecided, and only one wanted to leave the decision to others compared with 29% of controls (p=0.014). Most intervention patients did not want to be resuscitated. More wishes of intervention patients were known (p=0.006) and documented (p=0.021). There was no statistical difference between groups regarding resuscitation wish fulfilment. Most patients in both groups wished to die at home. For 53 patients, the wish of last place of care fulfilment could be monitored, which was more often correctly documented in the medical chart (p=0.001), and was fulfilled during follow-up (p=0.045) in the intervention compared with control group. Regarding fulfilment of other end-of-life wishes (online supplementary file 2), hospitalisation and mortality (table 5), there was no statistical differences between groups.



n=number of patients, IC=informed consent

Figure 1 Study flowchart according to Consolidated Standards of Reporting Trials.

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Table 3 Baseline characteristics of all screened patients

	Included patients n (%) (n=115)	Non-participants n (%) (n=88)	Excluded patients n (%) (n=1261)	P values
Gender (male)	88 (77)	47 (53)	726 (58)	<0.001
Age mean (SD)	64.3 (15)	68.1 (14)	67.6 (15)	0.07
Frequent admissions (yes)	47 (41)	14 (47)	192 (43)	0.84
Difficult to control symptoms (yes)	96 (84)	20 (67)	330 (74)	0.05
Complex care requirements (yes)	6 (5)	2 (7)	99 (22)	<0.001
Decline in function (yes)	45 (39)	9 (30)	228 (51)	0.01
Surrogate (yes)	92 (80)	68 (77)	–	0.64
Clear end-of-life preferences (yes)	44 (38)	47 (53)	–	0.03
Advance directive (yes)	38 (33)	38 (43)	–	0.14
Want to be resuscitated				0.21
Yes	23 (20)	11 (13)	–	
Yes, depending on the prognosis	47 (41)	33 (38)		
No	45 (39)	44 (50)		

n=number of patients. SD=standard deviation

Secondary outcomes

Advance directives and surrogacy

At baseline, about one-third of patients had an AD and three quarters had an appointed surrogate decision-maker in both groups (table 4). At discharge, most intervention patients reported having an AD and an appointed surrogate decision-maker compared with 33% having an AD (p<0.001) and 82% having an appointed surrogate decision-maker (p=0.1) in the control group (table 6).

Six months after discharge, all patients interviewed in the intervention group had an appointed surrogate decision-maker and an AD, compared with controls where 77% had an appointed surrogate (p=0.04) and 44% had an AD (p=0.004).

Decisional conflict, stress, anxiety and depression

Decisional conflict in patients and surrogates regarding medical treatment in future emergency situations was significantly lower in the intervention compared with control groups at discharge (p<0.001, patients only) and 6 months after discharge or intervention (patients and surrogates p<0.001) (table 6). Anxiety and depression scores were higher in surrogates than in patients in both groups with no statistical difference between groups. Three months after death, the impact of the event on surrogates was extremely high in both groups, with scores >33, indicating post-traumatic stress syndrome, which warranted treatment in 77% of surrogates in the intervention group compared with 94% in the control group. The mean difference reached statistical significance for a lower impact of the event in the intervention group in multiple imputation data sets (MI p=0.03) (table 6).

DISCUSSION

Medical services around the world aim to deliver high-quality patient-centred care at the end of life, including support for surviving relatives and to deliver this high-quality care in the place where the patient wants to be cared for until death. Worldwide, including Switzerland, most patients prefer to die at home.[15 34] Yet, most patients in most countries die in an institution (eg, hospital or nursing home).[35] ACP was developed as a tool to bridge the gap between the 'is' and the 'ought', a goal not properly addressed by ADs completed by patients on their own.[3–7 10] Most trials evaluating facilitation of ACP have assessed the impact on care of elderly inpatients or patients in nursing homes[3–7 10] and no trial has combined ACP facilitation with evidence-based decision aids. The ongoing ACTION study[36] is testing the effect of a Respecting Choices-based ACP facilitation on hospitalised patients with cancer in a multinational, multicentre cluster-randomised trial in six countries. This study promises to deliver important insights on the impact of highly skilled ACP facilitation in this patients group. Different from our trial, quality of life and symptom burden 2.5 months post intervention is the primary outcome and decision aids are not included in the intervention. Our pragmatic randomised controlled trial is therefore unique in investigating whether a newly introduced ACP facilitation strategy using decision aids could further improve patient-centred care and in measuring concordance of caregiver knowledge and fulfilment of treatment and care preferences in severely ill medical inpatients, predominantly suffering from cancer.

Feasibility of ACP for severely ill patients in an acute hospital setting

As indicated in table 3, although we screened 1464 patients, due to the study protocol, we randomised only 115 patient–surrogate dyads. Importantly, ACP can support surrogates of patients not fully capable of decision-making, patients not able to name a surrogate or a responsible physician or patients speaking different languages. However, these groups are under-represented in most ACP studies including ours. We obtained some information on the characteristics of excluded patients and

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Table 4 Baseline characteristics of the two randomised patient groups

	Intervention n (%) (n=57)	Control n (%) (n=58)	P values
Gender (male)	40 (70)	48 (83)	0.17
Age mean (SD)	64.74 (15)	63.88 (15)	0.76
Range (min–max)	75 (19–94)	71 (19–90)	
Frequent admissions (yes)	19 (33)	28 (48)	0.11
Difficult to control symptoms (yes)	48 (84)	48 (83)	0.83
Complex care requirements (yes)	4 (7)	2 (3)	0.44
Decline in function (yes)	23 (40)	22 (38)	0.79
Surrogate (yes)	43 (75)	49 (85)	0.23
Clear end-of-life preferences (yes)	24 (42)	20 (35)	0.52
Advance directive (yes)	20 (35)	18 (31)	0.64
Want to be resuscitated			0.34
Yes	11 (19)	12 (21)	
Yes, depending on the prognosis	20 (35)	27 (47)	
No	26 (46)	19 (33)	
Ward			1.00
Dermatology	5 (9)	5 (9)	
Internal medicine	5 (9)	7 (12)	
Nephrology	3 (5)	3 (5)	
Neurology	5 (9)	5 (9)	
Oncology	16 (28)	16 (28)	
Radio-oncology	17 (30)	18 (31)	
Haematology	6 (11)	4 (7)	
Religious affiliation (yes)	44 (77)	46 (79)	0.96
Main diagnosis			0.43
Cancer	51 (90)	49 (85)	
Other	6 (11)	9 (16)	
Highest education			0.54
Lower education	3 (5)	1 (2)	
Upper education	29 (51)	33 (57)	
Higher education	25 (44)	24 (41)	
Citizenship			0.49
Swiss	48 (84)	52 (90)	
EU	5 (9)	5 (9)	
Other	4 (7)	1 (2)	
Civil status			0.28
In a relationship	39 (68)	36 (62)	
Single	5 (9)	11 (19)	
Separated	13 (23)	11 (19)	

n=number of patients. SD=standard deviation

non-participants through capturing full screening results and the non-participation questionnaire, but cannot exclude non-response bias. Our screening results show that introducing ACP to patients with a positive 12 months surprise question in an acute hospital setting may be too late or not feasible. If hospital stays are too short without scheduled follow-up, or patients are too sick, ACP consultations may be impeded. Unfortunately, ACP is not routinely initiated in the ambulatory setting by general practitioners or specialists even in countries with a highly developed palliative care culture.[37] It is therefore important that severely ill patients be exposed to ACP in all possible places of care, including the acute hospital setting, given our current findings which are consistent with those of an Australian trial on elderly medical inpatients, aged>80.[6]

One size does (not always) fit all: differences between patient groups

Compared with similar studies, our refusal rate was high, mostly triggered by surrogates, who stated that they felt too stressed. In the Australian study,[6] 0% of the intervention and 15% of control group surrogates indicated a post-traumatic stress syndrome on the impact of event scale after death

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Table 5 Primary outcomes of patients' wishes known and fulfilled 6 months after discharge/intervention or after death

		Intervention n (%)	Control n (%)	P values	Missings (intervention/ control)	MI P values
Resuscitation	Do you want to be resuscitated?			0.014	32/21	0.037
	Yes	6 (24)	13 (35)			
	No	18 (72)	13 (35)			
	Leave decision to surrogate or physician	1 (4)	5 (14)			
	Undecided	0 (0)	6 (16)			
	Congruency between patient, surrogate and physician			0.006	23/12	0.008
	Present	21 (62)	14 (30)			
	Absent	13 (38)	32 (70)			
	Wish documented			0.021	22/13	0.041
	Yes	31 (89)	29 (64)			
	No	4 (11)	16 (36)			
	Wish fulfilled			0.821	12/2	1.000
	Yes	6 (13)	5 (9)			
	No	1 (2)	2 (4)			
	Unclear/not applicable	38 (84)	49 (88)			
Last place of care	Preferred last place of care?			0.824	32/21	0.994
	At home	17 (68)	20 (54)			
	Nursing home	2 (8)	4 (11)			
	Hospice	1 (4)	1 (3)			
	Hospital	4 (16)	7 (19)			
	Intensive care unit	0 (0)	0 (0)			
	Unsure	0 (0)	2 (5)			
	Don't know	1 (4)	3 (8)			
	Congruency between patient, surrogate and physician			0.059	23/12	0.039
	Present	15 (44)	11 (24)			
	Absent	19 (56)	35 (76)			
	Wish documented			0.001	22/13	0.002
	Yes	17 (49)	6 (13)			
	No	18 (51)	39 (87)			
	Wish fulfilled			0.045	12/2	0.079
	Yes	13 (29)	6 (11)			
	No	7 (16)	7 (13)			
	Unclear / not applicable	25 (56)	43 (77)			
Hospitalisation	Were you hospitalised in the past six months?			0.295	22/14	0.446
	Yes	19 (54)	29 (66)			
	No	16 (46)	15 (34)			
Mortality	When did the patient die?			0.301	12/2	0.837
	Within 6 months after inclusion	19 (42)	16 (29)			
	After 6 months after inclusion	11 (24)	14 (25)			
	Alive/unclear	15 (33)	26 (46)			

n=number of patients.
MI, multiple imputation.

while in our study we found the rates to be 77% and 94%, respectively (table 6, scores of the impact of event scale≥33). The high level of surrogate stress and depression in younger patients, suffering from oncological disease, is known.[38] Focusing on general goals of care in ACP is very helpful.[4–6] Yet, most of our intervention patients used explicit evidence-based information provided in decision aids to reach decisions on specific treatments (such as resuscitation or tube feeding) and expressed concrete end-of-life wishes in concordance with their general goals of care. We therefore suggest that, compared with elderly patients, younger severely -ill patients may have a greater need to express concrete wishes regarding specific treatments, which can be facilitated through the use of focused decision aids.

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Table 6 Secondary outcomes: advance directive, surrogacy, decisional conflict, depression, anxiety and impact of death on surrogate decision-maker

			Intervention Mean (SD)	Control Mean (SD)	P values	Missings (intervention/ control)	MI P values
Patient discharge/ intervention	HADS anxiety	Mean (SD)	4.22 (3.87)	4.44 (3.25)	0.770	20/4	0.820
		Score≥8 n (%)	n=11 (30)	n=11 (20)	0.310	20/4	0.853
	HADS depression	Mean (SD)	5.73 (4.24)	5.04 (3.67)	0.42	20/4	0.328
		Score≥8 n (%)	n=12 (32)	n=15 (28)	0.630	20/4	0.903
	Decisional conflict	Mean (SD)	13.47 (15.08)	36.28 (24.44)	<0.001	20/7	0.000
	Advance directives	Yes n (%)	34 (92)	18 (33)	<0.001	20/4	0.000
	Surrogate	Yes n (%)	35 (95)	44 (82)	0.100	20/4	0.256
Patient 6 months after discharge/intervention	HADS anxiety	Mean (SD)	3.72 (2.79)	3.9 (3.73)	0.83	32/19	0.712
		Score≥8 n (%)	n=3 (12)	n=8 (21)	0.353	32/19	0.114
	HADS depression	Mean (SD)	4.68 (3.36)	4.41 (3.44)	0.76	32/19	0.721
		Score≥8 n (%)	n=5 (20)	n=7 (18)	0.839	32/19	0.602
	Decisional conflict	Mean (SD)	14.44 (13.10)	33.51 (23.99)	<0.001	32/20	0.000
	Advance directives	Yes n (%)	27 (100)	17 (44)	0.004	32/19	0.001
	Surrogate	Yes n (%)	27 (100)	30 (77)	0.040	32/19	0.009
Surrogate 6 months after discharge/intervention or 3 months after death	HADS anxiety	Mean (SD)	6.11 (5.20)	6.35 (3.41)	0.80	19/6	0.748
		Score≥8 n (%)	n=15 (40)	n=19 (37)	0.777	19/6	0.828
	HADS depression	Mean (SD)	5.45 (5.74)	5.37 (4.32)	0.94	19/6	0.889
		Score≥8 n (%)	n=10 (26)	n=10 (19)	0.431	19/6	0.543
	Decisional conflict	Mean (SD)	20.18 (14.96)	40.36 (23.42)	<0.001	33/23	0.000
	Impact of event	Mean (SD)	44.15 (15.04)	47.56 (12.90)	0.52	44/42	0.034
		Score≥33 n (%)	n=10 (77)	n=15 (94)	0.260	44/42	0.340

n=number of patients.
HADS, Hospital Anxiety and Depression Scale ; MI, multiple imputation.

Strengths and limitations

The main strength of our study is the double-blind randomised controlled pragmatic study design to determine the feasibility and impact of introducing an in-house ACP facilitation programme. We gained important insights regarding who may benefit, and for whom and to what extent, an ACP programme in an acute hospital setting may be too late or not feasible (table 3). Other strengths of our study are the inclusion of decision aids for more specific and informed decision-making, the length of follow-up, the inclusion of surrogates, physicians and medical record data and their triangulation, allowing construction of a tool to assess concordance of patients wishes and concrete wish fulfilment. Our sample is clearly skewed towards male patients with cancer; however, we did not find any evidence in the literature on gender preferences impacting ACP and therefore expect our findings to be generalisable to both genders. Our observation that surrogates were not only extremely stressed, but also very influential regarding the decision to participate, with female surrogates being more positive towards participation (which might explain the gender bias), remains anecdotal but deserves further study. Our initial screening based on the surprise question answered by physicians likely led to the predominance of patients with cancer being included in the study as the prognosis is generally easier to anticipate in this group. Other studies on illness trajectories have also discussed the challenges of ACP and prognostication in internal medicine conditions other than cancer.[39 40] Our study therefore under-represents the potential benefit of ACP for general internal medicine patients in an acute hospital setting. In general, the study was underpowered for the effective evaluation of the impact of ACP on fulfilment of patient's wishes, and we were not able to recruit the number of patients needed according to our power calculating. The significant differences that were found therefore may underestimate the true impact of ACP. In addition, we cannot rule out some selection bias as 91 patients meeting inclusion criteria were excluded by ward physicians who made their own assessment of eligibility or openness of their patients towards conversations on future care (figure 1).

Complete blinding in a complex intervention is much more difficult compared with pharmaceutical trials using placebo pills. To maximally ensure blinding we delivered a 'placebo conversation' to patients, informed patients, physicians and surrogates that we were testing the effect of two sorts of in-hospital conversations on post-discharge care, and assessed the endpoint of concrete end-of-life wishes within 6 months after discharge to prevent

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an influence of the questions addressing ACP on study participants, including physicians. The trial benefited from the fact that legal requirements for ADs were only recently introduced and ACP did not exist in Switzerland at the time the trial recruitment began, making it less likely that study participants would deduce the study goal. Yet, we cannot be fully sure that the aim of the study and the assignment of patients to the intervention group was not understood by study participants, especially participating physicians. Further, we could not establish full blinding of observers since members of the study team screened and interviewed patients, surrogates, physicians and medical records. Outcome evaluation in medical records and congruency coding (tables 1 and 2) was however monitored by a blinded study member to minimise the effect of the observers being unblinded.

Due to the need to preserve blinding during the study period, we could not introduce a (potentially more beneficial[41]) regional approach, disseminate information on ACP and deliver continuous medical education to general practitioners, emergency physicians and specialised nurses in the ambulatory setting which may have reduced the positive impact of ACP on patients' end-of-life care. A further limitation of the study is the number of missing values (tables 5 and 6) due to the endpoints being measured 6 months after discharge in a very sick ambulatory population, among whom many were too burdened to answer or who had already died, whose surrogates sometimes felt too stressed for an interview, were lost to follow-up, had incomplete data in their medical charts or their attending physician did not want to cooperate with the study team. Through our study design of combining data on patients wishes with data from surrogates, physicians and the medical chart and using multiple imputation of all patients included, we tried to minimise the effect of missing not-at-random data and obtained endpoint data in all included patients who did not withdraw their informed consent (figure 1).

CONCLUSION

Introducing a 2-day ACP educational programme, followed by continuous coaching based on Respecting Patient Choices and beizeiten begleiten for non-physician hospital staff, and offering ACP consultation during hospital stay or at follow-up in regular ambulatory consultations, is feasible for severely ill adult patients with acute difficult-to-control symptoms and minor complex care requirements. One to three facilitation sessions with trained ACP facilitators helped reduce decisional conflict for emergencies and assisted patients and surrogates to make informed choices on future care. In-house ACP facilitation also increased the knowledge of attending physicians of patients' wishes, and the documentation of wishes in medical records, slightly reduced the impact of the death of a loved one on surrogates and increased the wish fulfilment of patients regarding last place of care. Future studies should focus on concrete wish fulfilment (rather than only wishes known), the effect of ACP on broader internal medicine and surgical patients, patients who cannot make decisions themselves and patients without family or from different cultural backgrounds. Screening strategies should develop better possibilities to identify non-cancer patients who may be approaching their end of life. ACP programmes targeted to younger severely ill patients should not only include information on general goals-of-care but also deliver evidence-based decision aids and concrete emergency plans in order to better address the need of these patients.

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Contributors TK was responsible for the concept of materials, ACP facilitation training, study procedures and statistical analysis. She wrote the first draft of the article to which all other authors also substantially contributed during writing up the final manuscript and the revised version of the article.

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AB in collaboration with FV was responsible for the statistical analysis of the raw data; wrote the statistical analysis part of the article; and made substantial contributions to the revised version of the article. IK and TO collaborated in the development of the educational programme and ACP documentation, were part of the study team, informed patients about the study, and obtained patient data. NBA and CM have been involved in the conceptualization of the study, have reviewed an earlier draft for important intellectual content and have approved the final version. BL together with TK developed the foundation of the ACP concept of the educational programme. In collaboration with TK she was responsible for the design of the study materials, especially the decision aids and the ACP documentation. She was primarily responsible for the educational programme, conducted educational sessions, was responsible for keeping contact with the unitsn and as part of the study team, informed patients about the study, and obtained patient data.

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Competing interests TK, IK, TO and BL work on implementation of ACP in Switzerland and have therefore received honorarium for talks and education on ACP or for work as counsellors of patients regarding ACP.

Patient consent Not required.

Ethics approval The study was approved by the research ethics committee of the Canton of Zurich, with the study number KEK-ZH 2012–0093 and was registered with the trial number NCT01914848.

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ACP facilitation training DAY 1

Timetable: 9 am – 4:30 pm

9.00 – 9.05	**Welcome**
9.05 – 9.25	**Introduction of the participants including their expectations**
9.25 – 9.30	**Aims of the training program**
9.30 – 9.45	**Introduction of the ACP concept**
9.45 – 10.00	**Exchange of experience with the AD the participants had to fill in:** What was easy? What kind of support would be useful
10.00 – 10.20	**Good Beginning**/ How to start a conversation
10.20 – 10.50	**Pairs: Starting a conversation Situations:** 1. Patient just returned from an intervention, is tired. 2. Patient awakening from his nap 3. Patient had visitors and doesn't want to talk **Exchange of experience**
10.50 – 11.05	**Break**
11.05 – 11.20	**Insecurity and stress of the counsellor during a session**
11.20 – 12.00	**How to name a substitute decision maker?**
12.00 – 12.30	**Exchange of experiences: daily practice until now plenum**
12.30 - 13.15	**Lunch Break**
13.15 – 13.40	**Discussion of values-** Role play by trainers
13.40 – 14.00	**Legal background of ACP**
14.00 – 14.15	**General Goals of Care-** Video
14.15 – 14.30	**Break**
14.30 – 15.00	**Emergency form (ÄNO/POLST) and how to use it**
15.00 - 16.00	**Exercise in pairs: Fill in an emergency form (ÄNO/POLST) of the role play patient based on his/her General Goals of Care:** What would he/she have wanted?
16.00 – 16.10	**Information concerning homework: Fill in a complete AD with a friend or relative**
16.10 – 16.30	**Open questions and good bye**

ACP facilitation training DAY2

Timetable: 9am – 4pm

9.00 – 9.05	**Welcome**
9.05 – 9.55	**Questions concerning the study plan**
10.00 – 10.30	**Experiences with homework**
10.30 – 10 .45	**Break**
10.45 – 11.30	**Interaction between General Goals of care and Decision Aids** Medical background for goals of care, examples Logic of the AD including emergency forms
11.30 – 11.50	**Excercise:** How to recognize inconsistant/invalid ADs (betwee values, goals of care, medical measures)
11.50 – 12 .30	**Discussion**
12.30 – 13.15	**Lunch break**
13.15 – 13.30	**Introduction of the following exercise**
13.30 – 14.30	**Role play (pairs with a observer)**

	Fill in an AD 1. Medical situation: COPD patient 2. Relationship conflict, surrogate afraid to take responsibility 3. No medical indication for CPR but patient wants «ALL»
14.30 – 15.00	**Exchange of experiences**
15.00 – 15.15	**Break**
15.30 – 15. 45	**Information about the training sessions with the actors**
15.30 – 15. 45	**Open questions**
15. 45 – 16.00	**Evaluation and good-bye**

Follow-up: Individual coaching support of facilitators by the MAPS study team ACP trainers up to 10 hours; ACP facilitation meetings every two months to exchange experiences

Appendix: Supplementary file

Table of contents

1. Results

1.1. Tables

1.1.1. Table 1. Primary outcomes with multiple imputation (MI)

	Intervention n (%)	Control n (%)	OR (CI) Difference % (CI)	P-value	Missings (Intervention / Control)	Intervention MI n (%) (n=57)	Control MI n (%) (n=58)	OR (CI) Difference % (CI)	P-value OR (CI)
Resuscitation									
Do you want to be resuscitated?				0.014	32/21				0.037
Yes	6 (24)	13 (35)				19 (33)	19 (32)		
No	18 (72)	13 (35)				33 (58)	21 (36)		
Leave decision to surrogate or physician	1 (4)	5 (14)				6 (10)	11 (18)		
Undecided	0 (0)	6 (16)				0 (0)	8 (13)		
Congruency between patient, surrogate and physician			3.69 (1.45,9.40)	0.006	23/12			3.25 (1.36,7.74)	0.008
Present	21 (62)	14 (30)	31 (10.27,52.39)			34 (60)	18 (32)	28 (8.25,48.30)	
Absent	13 (38)	32 (70)				24 (40)	40 (68)		
Wish documented			3.79 (1.23,11.75)	0.021	22/13			3.50 (1.05,11.67)	0.041
Yes	31 (89)	29 (64)	24 (6.61,41.64)			48 (85)	36 (62)	22 (3.33,41.67)	
No	4 (11)	16 (36)				10 (15)	22 (38)		
Wish fulfilled				0.821	12/2				1.000
Yes	6 (13)	5 (9)				7 (13)	5 (9)		
No	1 (2)	2 (4)				4 (7)	3 (5)		
Unclear / not applicable	38 (84)	49 (88)				46 (80)	50 (86)		
Last place of care									
Preferred last place of care?				0.824	32/21				0.994
At home	17 (68)	20 (54)				29 (51)	24 (42)		
Nursing home	2 (8)	4 (11)				13 (23)	10 (17)		
Hospice	1 (4)	1 (3)				8 (14)	7 (12)		
Hospital	4 (16)	7 (19)				6 (10)	10 (18)		
Intensive care unit	0 (0)	0 (0)				0 (1)	1 (2)		
Unsure	0 (0)	2 (5)				0 (0)	2 (4)		
Don't know	1 (4)	3 (8)				1 (2)	3 (5)		
Congruency between patient, surrogate and physician			2.51 (0.96,6.55)	0.059				2.42 (1.05,5.60)	0.039
Present	15 (44)	11 (24)	20 (-0.54,40.95)		23/12	26 (46)	15 (26)	20 (1.30,38.56)	
Absent	19 (56)	35 (76)				32 (54)	43 (74)		
Wish documented			6.14 (2.07,18.18)	0.001	22/13			4.74 (1.77,12.66)	0.002
Yes	17 (49)	6 (13)	35 (15.93,54.55)			28 (48)	10 (17)	32 (12.49,50.89)	
No	18 (51)	39 (87)				31 (52)	48 (83)		
Wish fulfilled				0.045	12/2				0.079
Yes	13 (29)	6 (11)				15 (27)	6 (10)		
No	7 (16)	7 (13)				12 (20)	8 (13)		
Unclear / not applicable	25 (56)	43 (77)				30 (53)	44 (76)		
Intubation									
Do you want to be intubated?				0.088	32/21				0.901
Yes	3 (12)	5 (14)				10 (17)	8 (13)		
No	15 (60)	14 (38)				26 (46)	20 (35)		
Leave decision to surrogate or physician	2 (8)	13 (35)				13 (22)	21 (37)		
Undecided	5 (20)	5 (14)				8 (15)	9 (15)		
Congruency between patient, surrogate and physician			2.59 (0.92,7.31)	0.072				2.57 (0.97,6.78)	0.057
Present	12 (35)	8 (17)	18 (-1.54,37.35)		23/12	22 (39)	12 (20)	19 (-0.15,38.04)	
Absent	22 (65)	38 (83)				36 (61)	47 (80)		
Wish documented			4.38 (1.44,13.39)	0.009	22/13			3.38 (1.30,8.84)	0.013
Yes	30 (86)	26 (58)	28 (9.43,46.45)			47 (82)	33 (57)	25 (6.48,42.88)	
No	5 (14)	19 (42)				12 (18)	25 (43)		
Wish fulfilled				1.000	12/2				0.990
Yes	2 (4)	3 (5)				2 (4)	3 (5)		
No	0 (0)	0 (0)				2 (4)	0 (1)		
Unclear / not applicable	43 (96)	53 (95)				53 (93)	55 (94)		
Dialysis									
Do you want to receive dialysis?				0.432	32/21				0.882
Yes	2 (8)	6 (16)				6 (11)	9 (15)		
No	10 (40)	8 (22)				22 (38)	14 (25)		
Leave decision to surrogate or physician	8 (32)	15 (41)				19 (33)	23 (39)		
Undecided	5 (20)	8 (22)				10 (17)	13 (22)		
Congruency between patient, surrogate and physician			1.78 (0.57,5.53)	0.317				1.63 (0.56,4.75)	0.368
Present	8 (24)	7 (15)	9 (-8.91,26.96)		24/12	16 (28)	11 (19)	9 (-9.71,26.86)	
Absent	25 (76)	39 (85)				42 (73)	47 (81)		
Wish documented			9.87 (2.84,34.29)	0.000	22/13			8.2 (2.50,26.89)	0.001
Yes	16 (46)	3 (7)	39 (21.01,57.09)			27 (47)	6 (10)	37 (19.40,54.62)	
No	19 (54)	42 (93)				31 (53)	52 (90)		
Wish fulfilled				0.635	12/2				1.000
Yes	1 (2)	3 (5)				1 (2)	3 (5)		
No	0 (0)	0 (0)				2 (4)	1 (1)		
Unclear / not applicable	44 (98)	53 (95)				54 (95)	54 (94)		
Artificial feeding									
Do you want to be artificially fed?				0.906	32/21				1.000
Yes	4 (16)	7 (19)				10 (18)	10 (18)		
No	13 (52)	17 (46)				24 (43)	24 (42)		
Leave decision to surrogate or physician	4 (16)	8 (22)				15 (26)	16 (27)		
Undecided	4 (16)	5 (14)				7 (13)	8 (13)		
Congruency between patient, surrogate and physician			2.52 (0.95,6.70)	0.064	23/12			2.81 (1.19,6.60)	0.018
Present	14 (41)	10 (22)	19 (-0.95,39.83)			27 (47)	14 (24)	23 (4.48,41.27)	
Absent	20 (59)	36 (78)				31 (53)	44 (76)		
Wish documented			5.75 (2.02,16.32)	0.001	22/13			4.41 (1.70,11.40)	0.002
Yes	18 (51)	7 (16)	36 (16.22,55.53)			30 (53)	12 (20)	32 (13.33,51.59)	
No	17 (49)	38 (84)				28 (47)	46 (80)		
Wish fulfilled				0.861	12/2				1.000
Yes	5 (11)	4 (7)				5 (10)	4 (7)		
No	0 (0)	1 (2)				4 (6)	2 (3)		
Unclear / not applicable	40 (89)	51 (91)				48 (84)	52 (90)		
Intravenous fluids									
Do you want to receive intravenous fluids?				0.727	32/21				1.000
Yes	12 (48)	18 (49)				22 (38)	25 (43)		
No	6 (24)	6 (16)				17 (30)	13 (22)		
Leave decision to surrogate or physician	4 (16)	10 (27)				13 (22)	15 (26)		
Undecided	3 (12)	3 (8)				5 (9)	5 (8)		
Congruency between patient, surrogate and physician			1.28 (0.51,3.23)	0.602	23/12			1.26 (0.51,3.11)	0.621
Present	13 (38)	15 (33)	6 (-15.59,26.85)			23 (40)	20 (34)	5 (-15.64,26.32)	
Absent	21 (62)	31 (67)				36 (61)	38 (66)		
Wish documented			2.09 (0.83,5.25)	0.118	22/13			1.85 (0.81,4.21)	0.146
Yes	24 (69)	23 (51)	17 (-3.75,38.67)			37 (65)	29 (51)	15 (-4.77,34.26)	
No	11 (31)	22 (49)				21 (35)	29 (50)		
Wish fulfilled				0.596	12/2				0.346
Yes	14 (31)	20 (36)				16 (28)	20 (35)		
No	1 (2)	0 (0)				5 (9)	1 (1)		
Unclear / not applicable	30 (67)	36 (64)				36 (63)	37 (64)		

(Continued) Table 1. Primary outcomes with multiple imputation (MI)

	Intervention n (%)	Control n (%)	OR (CI) Difference % (CI)	P-value	Missings (Intervention / Control)	Intervention MI n (%) (n=57)	Control MI n (%) (n=58)	OR (CI) Difference % (CI)	P-value OR (CI)
Antibiotics									
Do you want to receive antibiotics against pneumonia?				0.150	32/21				0.796
Yes	12 (48)	18 (49)				23 (40)	25 (43)		
No	4 (16)	4 (11)				15 (26)	12 (21)		
Leave decision to surrogate or physician	3 (12)	12 (32)				10 (18)	16 (28)		
Undecided	6 (24)	3 (8)				10 (17)	5 (8)		
Congruency between patient, surrogate and physician			2.23 (0.85,5.83)	0.103	23/12			2.16 (0.76,6.18)	0.15
Present	14 (41)	11 (24)	17 (-3.37,37.89)			24 (43)	15 (26)	17 (-6.10,40.33)	
Absent	20 (59)	35 (76)				34 (57)	43 (74)		
Wish documented			5.92 (2.22,15.81)	0.000	22/13			5.22 (2.16,12.62)	0.000
Yes	22 (63)	10 (22)	41 (20.54,60.73)			36 (62)	14 (24)	38 (19.80,56.49)	
No	13 (37)	35 (78)				23 (38)	44 (76)		
Wish fulfilled				1.000	12/2				0.918
Yes	13 (29)	16 (29)				15 (27)	16 (28)		
No	0 (0)	0 (0)				4 (7)	1 (1)		
Unclear / not applicable	32 (71)	40 (71)				38 (66)	41 (71)		
Sedation for symptom reduction									
Do you want to be sedated for symptom reduction?				0.278	32/21				0.501
Yes	10 (40)	14 (38)				20 (36)	19 (32)		
No	8 (32)	5 (14)				21 (36)	13 (22)		
Leave decision to surrogate or physician	5 (20)	13 (35)				12 (21)	20 (34)		
Undecided	2 (8)	5 (14)				4 (8)	7 (12)		
Congruency between patient, surrogate and physician			2.66 (0.91,7.84)	0.075	23/12			2.67 (0.95,7.48)	0.063
Present	11 (32)	7 (15)	17 (-1.71,35.98)			21 (37)	11 (18)	19 (-0.15,37.63)	
Absent	23 (68)	39 (85)				37 (63)	48 (82)		
Wish documented			3.31 (1.26,8.69)	0.015	22/13			2.85 (1.18,6.88)	0.02
Yes	17 (49)	10 (22)	26 (5.81,46.88)			28 (49)	15 (25)	24 (4.49,42.70)	
No	18 (51)	35 (78)				30 (51)	44 (75)		
Wish fulfilled				0.528	12/2				0.351
Yes	13 (29)	12 (21)				15 (26)	12 (21)		
No	0 (0)	0 (0)				5 (8)	1 (1)		
Unclear / not applicable	32 (71)	44 (79)				38 (66)	45 (78)		
Hospitalisation									
Were you hospitalised in the past six months?			0.61 (0.25,1.53)	0.295	22/14			0.7 (0.28,1.75)	0.446
Yes	19 (54)	29 (66)	-12 (-33.27,10.02)			31 (54)	37 (63)	-8.6 (-30.40,13.31)	
No	16 (46)	15 (34)				27 (46)	22 (37)		
Mortality									
When did the patient die?				0.301	12/2				0.837
Within six months after inclusion	19 (42)	16 (29)				23 (40)	17 (29)		
After six months after inclusion	11 (24)	14 (25)				16 (27)	15 (25)		
Lives/Unclear	15 (33)	26 (46)				19 (33)	27 (46)		

1.1.2. Table 2. Secondary outcome with multiple imputation (MI)

		Intervention Mean (SD)	Control Mean (SD)	OR or Difference (CI)	P-value	Missings (Intervention / Control)	Intervention MI Mean (SD) (n=57)	Control MI Mean (SD) (n=58)	OR or Difference (CI)	P-value
Patient Discharge	HADS Anxiety Mean(SD)	4.22 (3.87)	4.44 (3.25)	-0.22 (-1.77,1.32)	0.770	20/4	4.30 (3.29)	4.44 (3.18)	-0.14 (-1.34,1.06)	0.820
	Score ≥8 (%)	n=11 (30)	n=11 (20)	9.36 (-8.87,27.59)	0.310	20/4	11.6 (20.4)	11.0 (19.0)	1.39 (-13.26,16.03)	0.853
	HADS Depression Mean(SD)	5.73 (4.24)	5.04 (3.67)	0.69 (-1.02,2.40)	0.42	20/4	5.75 (3.63)	5.06 (3.58)	0.69 (-0.70,2.10)	0.328
	Score ≥8 (%)	n=12 (32)	n=15 (28)	4.65 (-14.59,23.90)	0.630	20/4	14.7 (25.8)	15.6 (26.9)	-1.11 (-18.92,16.71)	0.903
	Decisional Conflict Mean(SD)	13.47 (15.08)	36.28 (24.44)	-22.81 (-31.21,-14.40)	<0.001	20/7	13.54 (12.29)	36.37 (22.95)	-22.83 (-29.59,-16.07)	0.000
	Advance directives Yes (%)	34 (92)	18 (33)	19.22 (5.68,65.04)	<0.001	20/4	50.3 (88.2)	19.6 (33.8)	14.78 (5.43,40.20)	0.000
	Surrogate Yes (%)	35 (95)	44 (82)	3.3 (0.81,13.46)	0.100	20/4	51.2 (89.8)	47.0 (81.0)	2.1 (0.58,7.56)	0.256
Patient six months after discharge	HADS Anxiety Mean(SD)	3.72 (2.79)	3.9 (3.73)	-0.18 (-1.81,1.46)	0.83	32/19	3.77 (2.28)	3.99 (3.23)	-0.22 (-1.42,0.97)	0.712
	Score ≥8 (%)	n=3 (12)	n=8 (21)	-8.51 (-26.48,9.46)	0.353	32/19	3.1 (5.4)	8.3 (14.3)	-8.87 (-19.87,2.12)	0.114
	HADS Depression Mean(SD)	4.68 (3.36)	4.41 (3.44)	0.27 (-1.47,2.01)	0.76	32/19	4.68 (2.54)	4.47 (3.00)	0.21 (-0.94,1.36)	0.721
	Score ≥8 (%)	n=5 (20)	n=7 (18)	2.05 (-17.72,21.82)	0.839	32/19	5.6 (9.8)	7.6 (13.1)	-3.28 (-15.60,9.05)	0.602
	Decisional Conflict Mean(SD)	14.44 (13.10)	33.51 (23.99)	-19.07 (-28.46,-9.69)	<0.001	32/20	14.45 (9.02)	33.63 (19.58)	-19.18 (-24.84,-13.53)	0.000
	Advance directives Yes (%)	27 (100)	17 (44)	105.48 (4.25,2620.05)	0.004	32/19	57.0 (100.0)	25.5 (44.0)	232.22 (8.58,6287.37)	0.001
	Surrogate Yes (%)	27 (100)	30 (77)	20.97 (1.15,381.63)	0.040	32/19	57.0 (100.0)	42.8 (73.8)	55.08 (2.72,1114.58	0.009
Surrogate six months after discharge/intervention or three months after death	HADS Anxiety Mean(SD)	6.11 (5.20)	6.35 (3.41)	-0.24 (-2.18,1.69)	0.80	19/6	6.09 (4.43)	6.34 (3.30)	-0.25 (-1.73,1.24)	0.748
	Score ≥8 (%)	n=15 (40)	n=19 (37)	2.94 (-17.38,23.25)	0.777	19/6	18.7 (32.8)	20.3 (35.0)	-2.19 (-22.02,17.63)	0.828
	HADS Depression Mean(SD)	5.45 (5.74)	5.37 (4.32)	0.08 (-2.13,2.29)	0.94	19/6	5.46 (4.88)	5.34 (4.13)	0.12 (-1.58,1.83)	0.889
	Score ≥8 (%)	n=10 (26)	n=10 (19)	1.5 (0.55,4.07)	0.431	19/6	12.9 (22.6)	10.3 (17.8)	4.87 (-10.83,20.57)	0.543
	Decisional Conflict Mean(SD)	20.18 (14.96)	40.36 (23.42)	-20.18 (-30.19,-10.16)	<0.001	33/23	20.40 (10.04)	40.33 (18.34)	-19.93 (-25.42,-14.44)	0.000
	Impact of event Mean(SD)	44.15 (15.04)	47.56 (12.90)	-3.42 (-14.30,7.48)	0.52	44/42	44.27 (7.77)	47.68 (7.34)	-3.41 (-6.56,-0.26)	0.034
	Score ≥33 (%)	n=10 (77)	n=15 (94)	0.32 (0.05,2.31)	0.260	44/42	53.8 (94.4)	57.0 (98.3)	0.4 (0.06,2.62)	0.340

1.1.3. Table 3. Dyad congruency with multiple imputation (MI)

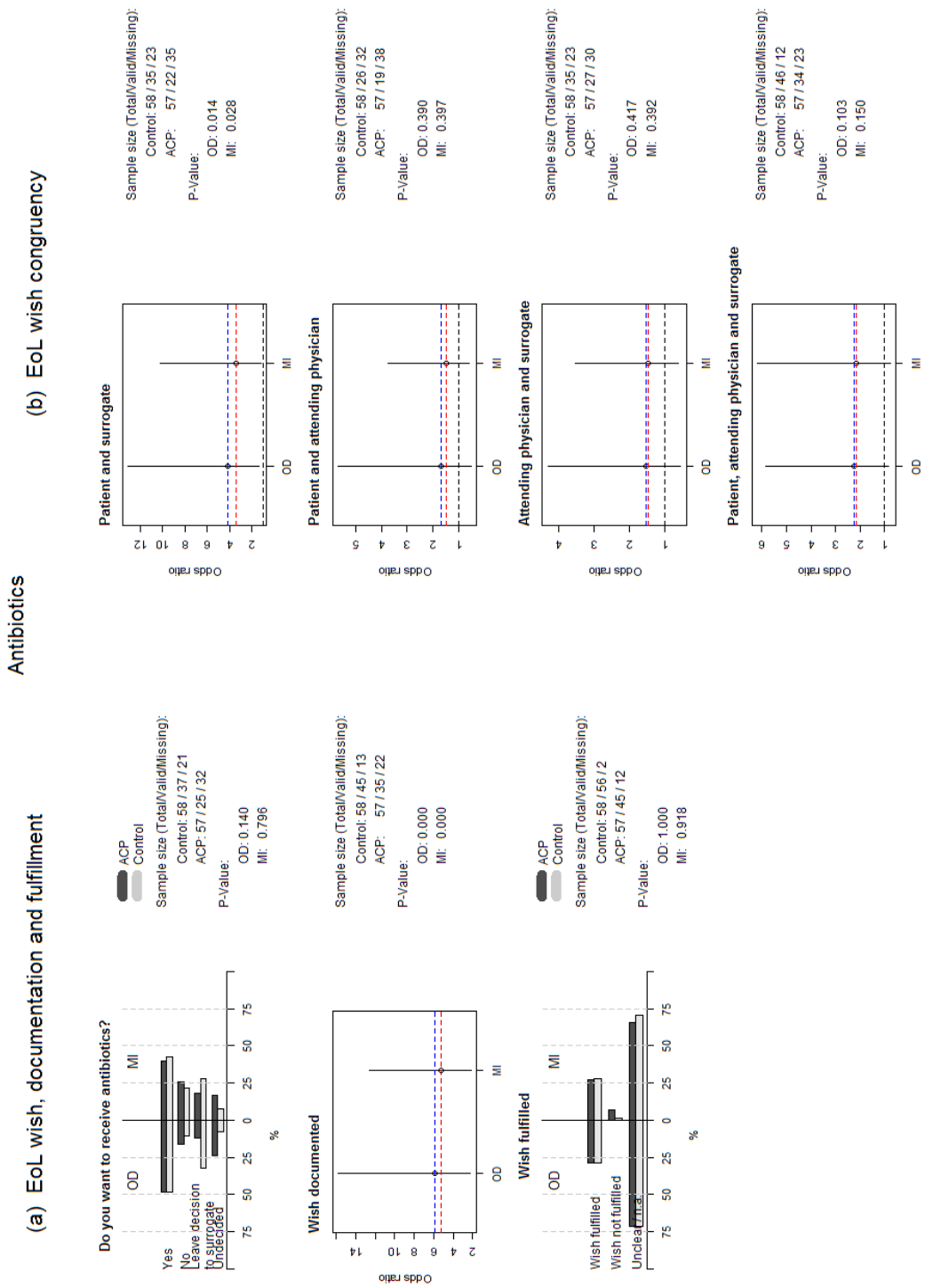
	Intervention n (%) (n=57)	Control n (%) (n=58)	OR (CI) Difference % (CI)	P-value OR (CI)	Missings (Intervention / Control)	Intervention MI n (%) (n=57)	Control MI n (%) (n=58)	OR (CI) Difference % (CI)	P-value OR (CI)
Resuscitation									
Congruency between patient and surrogate			8.89 (2.44,32.36)	0.001	35/23			5.82 (2.01,16.80)	0.001
Present	19 (86.4)	13 (37.1)	49.2 (27.73,70.71)			45.3 (79.5)	23.4 (40.3)	39.1 (18.32,59.93)	
Absent	3 (13.6)	22 (62.9)				12.7 (20.5)	34.6 (59.7)		
Congruency between patient and physician			4.57 (1.22,17.16)	0.024	38/36			3.15 (1.22,8.18)	0.018
Present	12 (63.2)	6 (27.3)	35.9 (7.31,64.46)			34.3 (60.2)	18.9 (32.6)	27.6 (5.98,49.20)	
Absent	7 (36.8)	16 (72.7)				23.7 (39.8)	39.1 (67.4)		
Congruency between surrogate and physician			4.16 (1.38,12.49)	0.011	30/27			2.83 (1.07,7.44)	0.035
Present	17 (63.0)	9 (29.0)	33.9 (9.70,58.16)			34.8 (61.1)	20.8 (35.9)	25.2 (2.83,47.56)	
Absent	10 (37)	22 (71)				23.2 (38.9)	37.2 (64.1)		
Last place of care									
Congruency between patient and surrogate			4.16 (1.27,13.65)	0.019	35/23			3.16 (1.22,8.15)	0.017
Present	18 (81.8)	17 (48.6)	42 (18.22,65.74)			42.6 (74.7)	28.2 (48.6)	29 (5.84,52.09)	
Absent	4 (18.2)	18 (51.4)				15.4 (25.3)	29.8 (51.4)		
Congruency between patient and physician			3.05 (0.80,11.60)	0.101	38/32			1.97 (0.81,4.81)	0.136
Present	8 (42.1)	5 (19.2)	22.9 (-4.00,49.75)			25.5 (44.7)	17.0 (29.3)	15.4 (-4.39,35.24)	
Absent	11 (57.9)	21 (80.8)				32.5 (55.3)	41 (70.7)		
Congruency between surrogate and physician			2.31 (0.79,6.76)	0.126	30/23			2.02 (0.84,4.88)	0.117
Present	12 (44.4)	9 (25.7)	18.7 (-4.95,42.41)			26.1 (45.8)	17.1 (29.5)	16.3 (-4.00,36.61)	
Absent	15 (55.6)	26 (74.3)				31.9 (54.2)	40.9 (70.5)		
Intubation									
Congruency between patient and surrogate			3 (0.98,9.14)	0.053	35/23			2.03 (0.77,5.32)	0.151
Present	12 (54.5)	10 (28.6)	26 (0.34,51.60)			29.7 (52.1)	20.3 (35.0)	17.1 (-5.89,40.10)	
Absent	10 (45.5)	25 (71.4)				28.3 (47.9)	37.7 (65)		
Congruency between patient and physician			4.44 (1.17,16.82)	0.028	38/33			2.72 (1.00,7.39)	0.049
Present	10 (52.6)	5 (20.0)	32.6 (5.25,60.02)			29.7 (52.1)	16.7 (28.8)	23.3 (1.09,45.53)	
Absent	9 (47.4)	20 (80)				28.3 (47.9)	41.3 (71.2)		
Congruency between surrogate and physician			1.91 (0.63,5.82)	0.254	30/24			1.81 (0.61,5.38)	0.288
Present	10 (37.0)	8 (23.5)	13.5 (-9.62,36.64)			23.5 (41.2)	16.3 (28.1)	13.1 (-10.86,37.11)	
Absent	17 (63)	26 (76.5)				34.5 (58.8)	41.7 (71.9)		
Dialysis									
Congruency between patient and surrogate			1.45 (0.48,4.41)	0.515	35/24			1.38 (0.58,3.28)	0.46
Present	9 (40.9)	11 (32.4)	8.6 (-17.32,34.43)			25.6 (44.9)	21.5 (37.1)	7.8 (-12.88,28.57)	
Absent	13 (59.1)	23 (67.6)				32.4 (55.1)	36.5 (62.9)		
Congruency between patient and physician			4.62 (1.24,17.20)	0.022	39/32			4.39 (1.61,11.93)	0.004
Present	9 (50.0)	4 (15.4)	34.6 (7.67,61.56)			30.5 (53.5)	12.2 (21.0)	32.5 (11.89,53.06)	
Absent	9 (50)	22 (84.6)				27.5 (46.5)	45.8 (79)		
Congruency between surrogate and physician			2.58 (0.73,9.18)	0.142	32/24			2.46 (0.95,6.39)	0.065
Present	7 (28.0)	4 (11.8)	16.2 (-4.43,36.90)			18.6 (32.6)	9.6 (16.6)	16.1 (-0.77,32.93)	
Absent	18 (72)	30 (88.2)				39.4 (67.4)	48.4 (83.4)		

(continued) Dyad congruency with multiple imputation (MI)

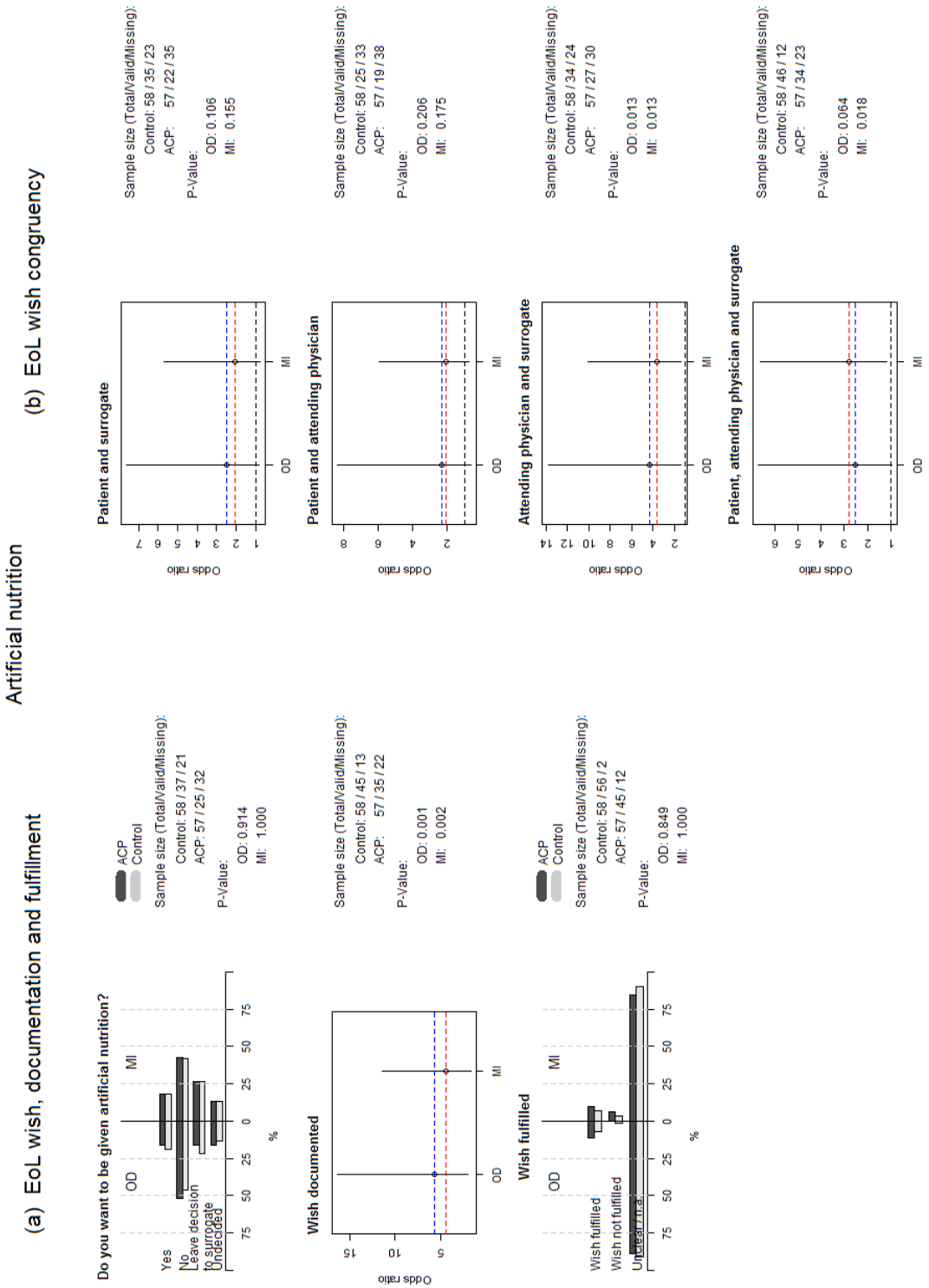
	Intervention n (%) (n=57)	Control n (%) (n=58)	OR (CI) Difference % (CI)	P-value OR (CI)	Missings (Intervention / Control)	Intervention MI n (%) (n=57)	Control MI n (%) (n=58)	OR (CI) Difference % (CI)	P-value OR (CI)
Artificial feeding									
Congruency between patient and surrogate			2.5 (0.82,7.60)	0.106	35/23			2.08 (0.76,5.71)	0.155
Present	11 (50.0)	10 (28.6)	21.4 (-4.27,47.13)			29.1 (51.1)	19.5 (33.6)	17.4 (-5.99,40.85)	
Absent	11 (50)	25 (71.4)				28.9 (48.9)	38.5 (66.4)		
Congruency between patient and physician			2.3 (0.63,8.39)	0.206	38/33			2.08 (0.72,5.97)	0.175
Present	8 (42.1)	6 (24.0)	18.1 (-9.70,45.91)			25.7 (45.1)	16.5 (28.4)	16.6 (-7.15,40.43)	
Absent	11 (57.9)	19 (76)				32.3 (54.9)	41.5 (71.6)		
Congruency between surrogate and physician			4.33 (1.36,13.83)	0.013	30/24			3.64 (1.32,10.06)	0.013
Present	13 (48.1)	6 (17.6)	30.5 (7.71,53.29)			28.3 (49.6)	12.5 (21.6)	28.1 (7.81,48.38)	
Absent	14 (51.9)	28 (82.4)				29.7 (50.4)	45.5 (78.4)		
Intravenous fluids									
Congruency between patient and surrogate			3.93 (1.26,12.28)	0.019	35/24			2.67 (0.99,7.19)	0.052
Present	15 (68.2)	12 (35.3)	32.9 (7.65,58.12)			35.2 (61.8)	22.0 (37.9)	23.8 (0.46,47.19)	
Absent	7 (31.8)	22 (64.7)				22.8 (38.2)	36 (62.1)		
Congruency between patient and physician			1.35 (0.38,4.80)	0.640	39/33			1.39 (0.60,3.26)	0.445
Present	7 (38.9)	8 (32.0)	6.9 (-22.12,35.90)			24.2 (42.5)	20.1 (34.7)	7.8 (-12.04,27.64)	
Absent	11 (61.1)	17 (68)				33.8 (57.5)	37.9 (65.3)		
Congruency between surrogate and physician			0.96 (0.33,2.76)	0.942	31/25			0.98 (0.43,2.23)	0.956
Present	10 (38.5)	13 (39.4)	-0.9 (-25.98,24.12)			23.3 (40.9)	24.0 (41.4)	-0.5 (-20.43,19.43)	
Absent	16 (61.5)	20 (60.6)				34.7 (59.1)	34 (58.6)		
Antibiotics									
Congruency between patient and surrogate			4.17 (1.34,13.03)	0.014	35/23			3.41 (1.14,10.18)	0.028
Present	13 (59.1)	9 (25.7)	33.4 (8.24,58.51)			33.9 (59.5)	17.6 (30.3)	29.1 (4.24,54.01)	
Absent	9 (40.9)	26 (74.3)				24.1 (40.5)	40.4 (69.7)		
Congruency between patient and physician			1.7 (0.51,5.70)	0.390	38/32			1.49 (0.59,3.73)	0.397
Present	9 (47.4)	9 (34.6)	12.8 (-16.20,41.71)			28.1 (49.3)	23.0 (39.7)	9.6 (-12.61,31.90)	
Absent	10 (52.6)	17 (65.4)				29.9 (50.7)	35 (60.3)		
Congruency between surrogate and physician			1.53 (0.55,4.30)	0.417	30/23			1.47 (0.61,3.54)	0.392
Present	12 (44.4)	12 (34.3)	10.2 (-14.31,34.62)			26.3 (46.1)	21.4 (36.9)	9.2 (-11.82,30.30)	
Absent	15 (55.6)	23 (65.7)				31.7 (53.9)	36.6 (63.1)		
Sedation for symptom reduction									
Congruency between patient and surrogate			2.62 (0.87,7.88)	0.087	35/23			2.09 (0.85,5.14)	0.108
Present	12 (54.5)	11 (31.4)	23.1 (-2.76,48.99)			29.8 (52.3)	20.0 (34.5)	17.8 (-3.53,39.13)	
Absent	10 (45.5)	24 (68.6)				28.2 (47.7)	38 (65.5)		
Congruency between patient and physician			4.02 (0.99,16.37)	0.052	39/32			3.35 (1.13,9.95)	0.030
Present	7 (38.9)	3 (11.5)	27.4 (1.70,53.00)			24.9 (43.7)	11.1 (19.1)	24.5 (3.01,46.09)	
Absent	11 (61.1)	23 (88.5)				33.1 (56.3)	46.9 (80.9)		
Congruency between surrogate and physician			3.57 (1.04,12.23)	0.043	31/23			2.9 (0.99,8.51)	0.053
Present	9 (34.6)	4 (11.4)	23.2 (2.08,44.29)			21.9 (38.4)	10.4 (17.9)	20.5 (0.97,40.01)	
Absent	17 (65.4)	31 (88.6)				36.1 (61.6)	47.6 (82.1)		

1.2. Graphs

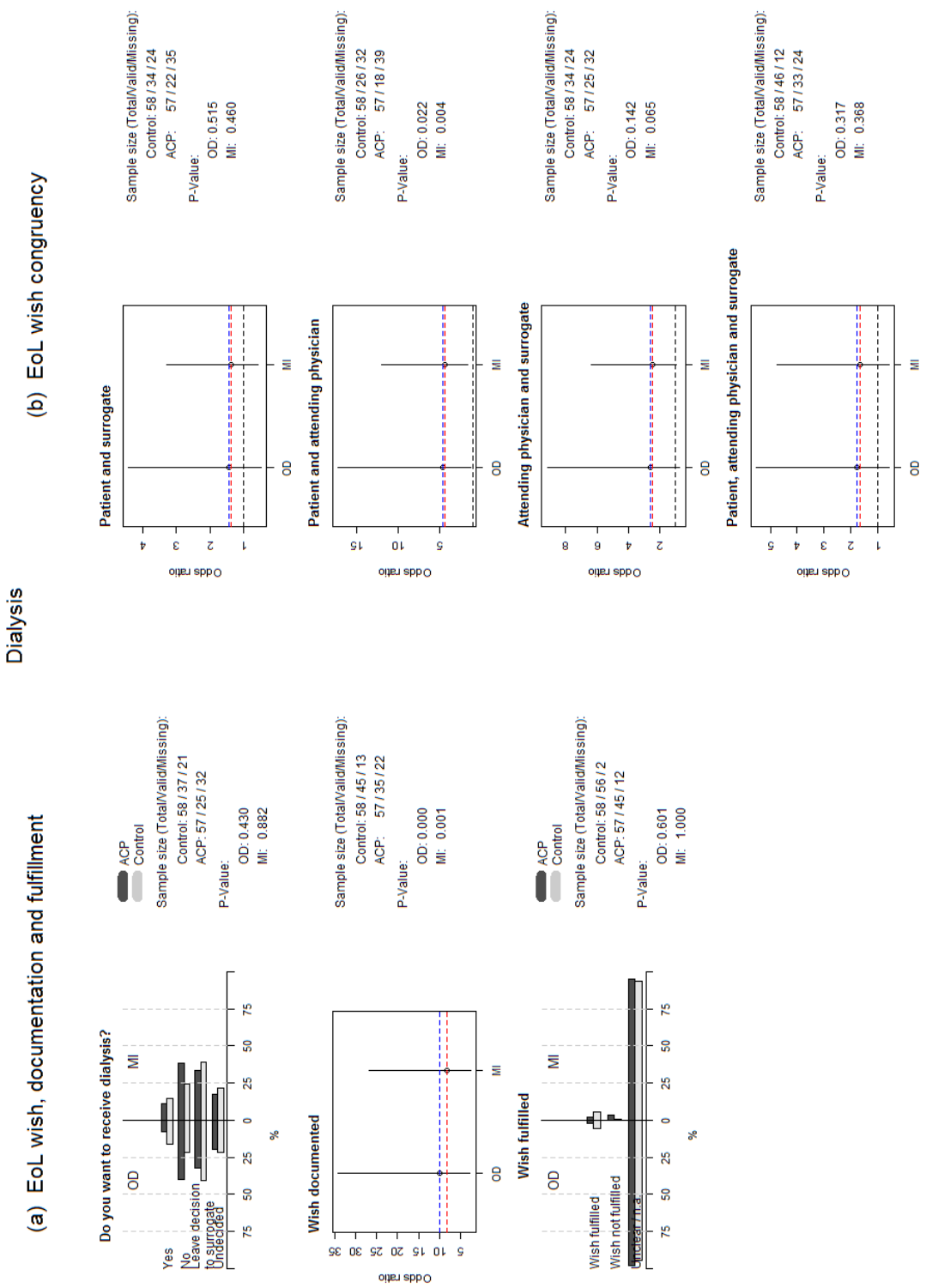
1.2.1. Antibiotics



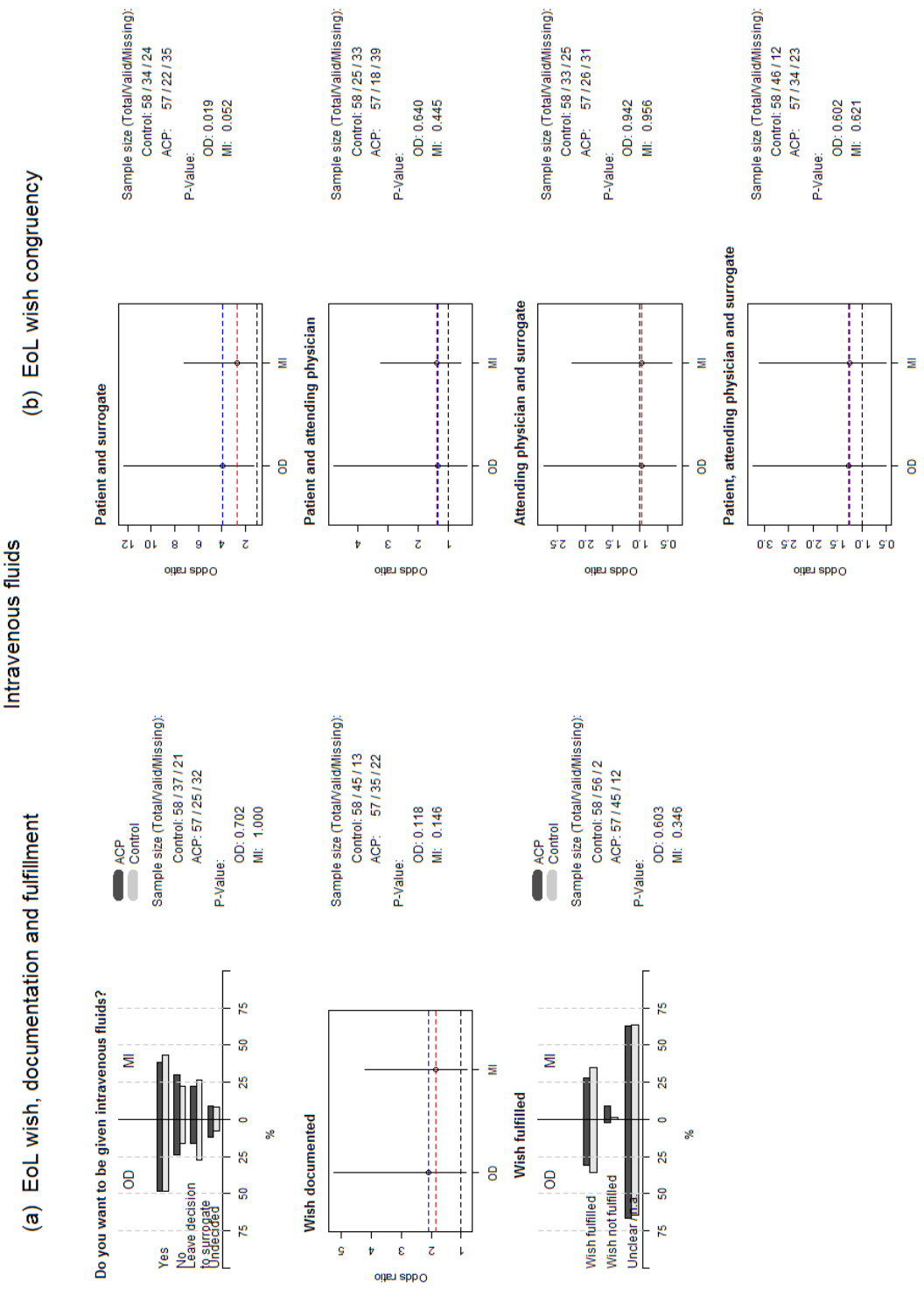
1.2.2. Artificial nutrition


Artificial nutrition
(a) EoL wish, documentation and fulfillment
(b) EoL wish congruency
Do you want to be given artificial nutrition?
Yes
No
Leave decision to surrogate
Undecided
OD
MI
%
ACP
Control
Sample size (Total/Valid/Missing):
Control: 58 / 37 / 21
ACP: 57 / 25 / 32
P-Value:
OD: 0.914
MI: 1.000
Wish documented
Odds ratio
Sample size (Total/Valid/Missing):
Control: 58 / 45 / 13
ACP: 57 / 35 / 22
P-Value:
OD: 0.001
MI: 0.002
Wish fulfilled
Wish fulfilled
Wish not fulfilled
Unclear n.a.
Sample size (Total/Valid/Missing):
Control: 58 / 56 / 2
ACP: 57 / 45 / 12
P-Value:
OD: 0.849
MI: 1.000
Patient and surrogate
Sample size (Total/Valid/Missing):
Control: 58 / 35 / 23
ACP: 57 / 22 / 35
P-Value:
OD: 0.106
MI: 0.155
Patient and attending physician
Sample size (Total/Valid/Missing):
Control: 58 / 25 / 33
ACP: 57 / 19 / 38
P-Value:
OD: 0.206
MI: 0.175
Attending physician and surrogate
Sample size (Total/Valid/Missing):
Control: 58 / 34 / 24
ACP: 57 / 27 / 30
P-Value:
OD: 0.013
MI: 0.013
Patient, attending physician and surrogate
Sample size (Total/Valid/Missing):
Control: 58 / 46 / 12
ACP: 57 / 34 / 23
P-Value:
OD: 0.064
MI: 0.018

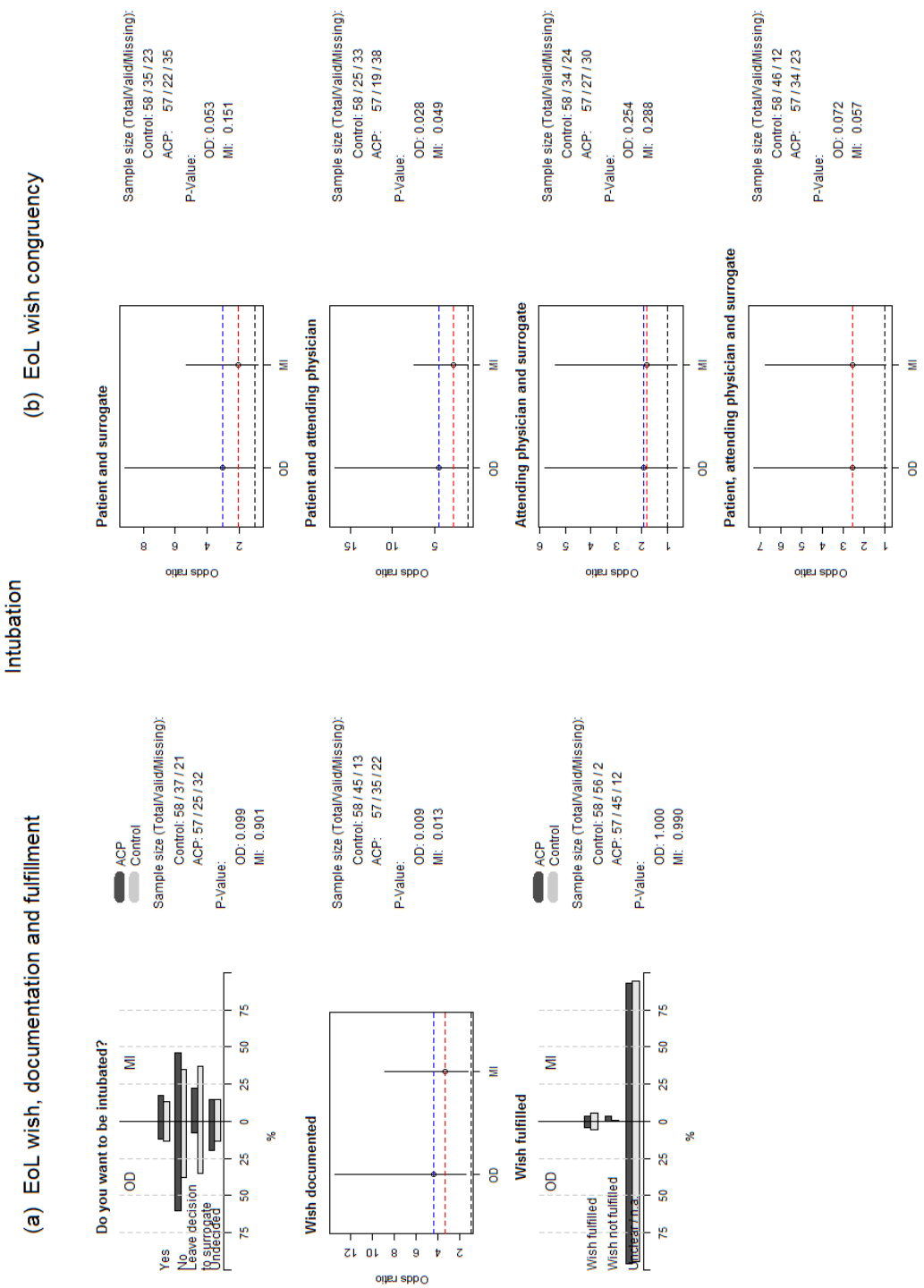
1.2.3. Dialysis



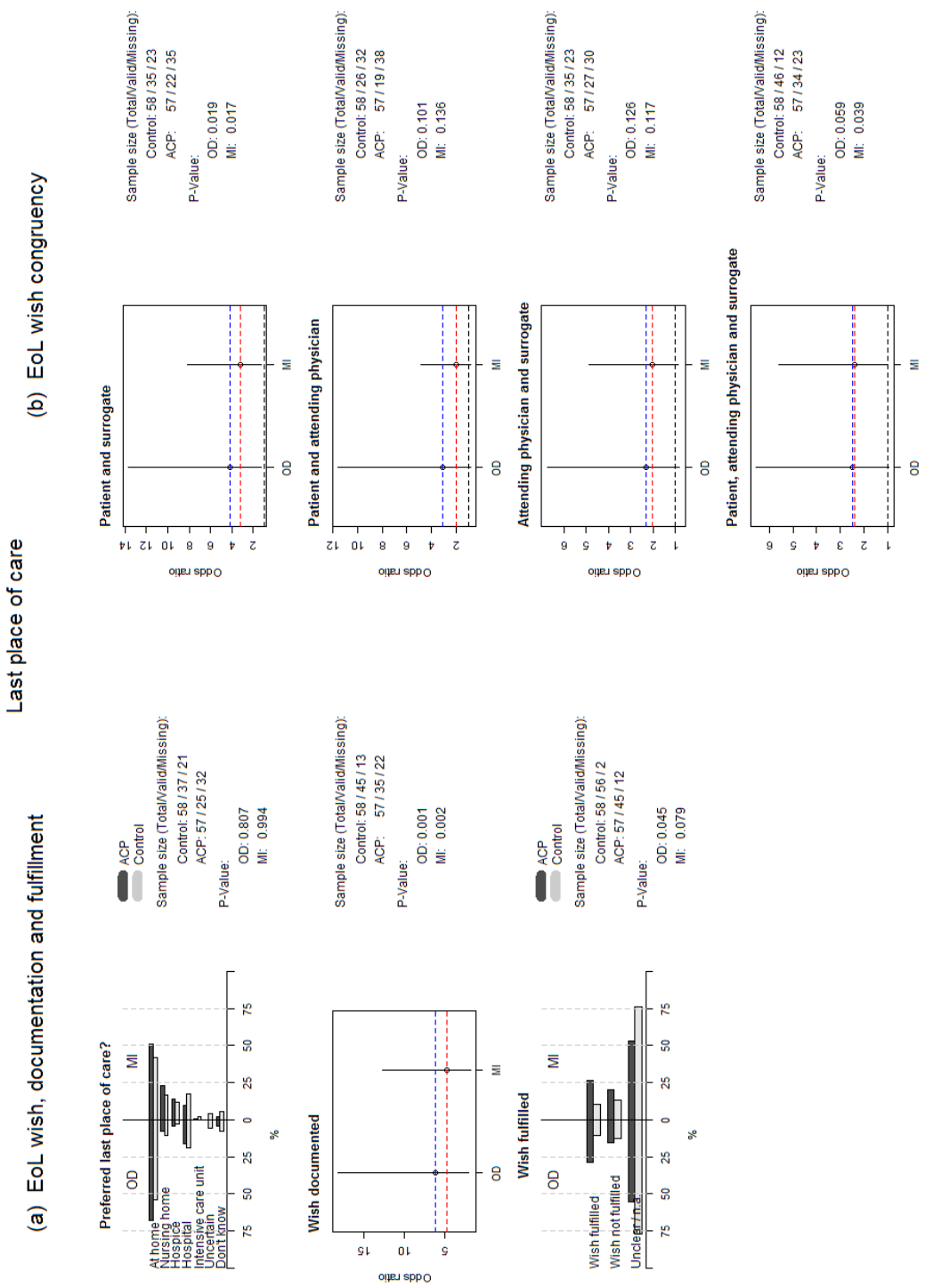
1.2.4. Intravenous fluids



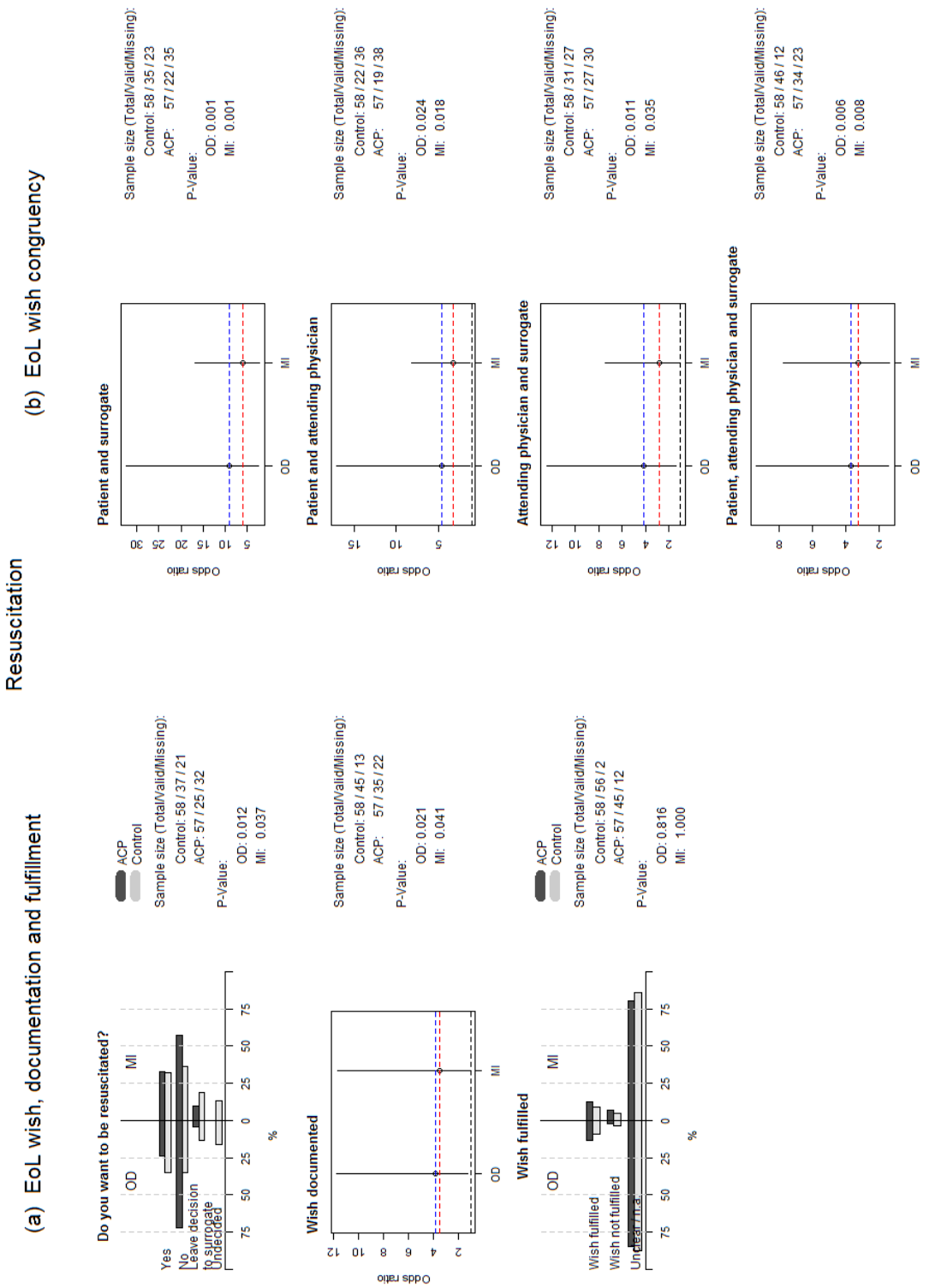
1.2.5. Intubation



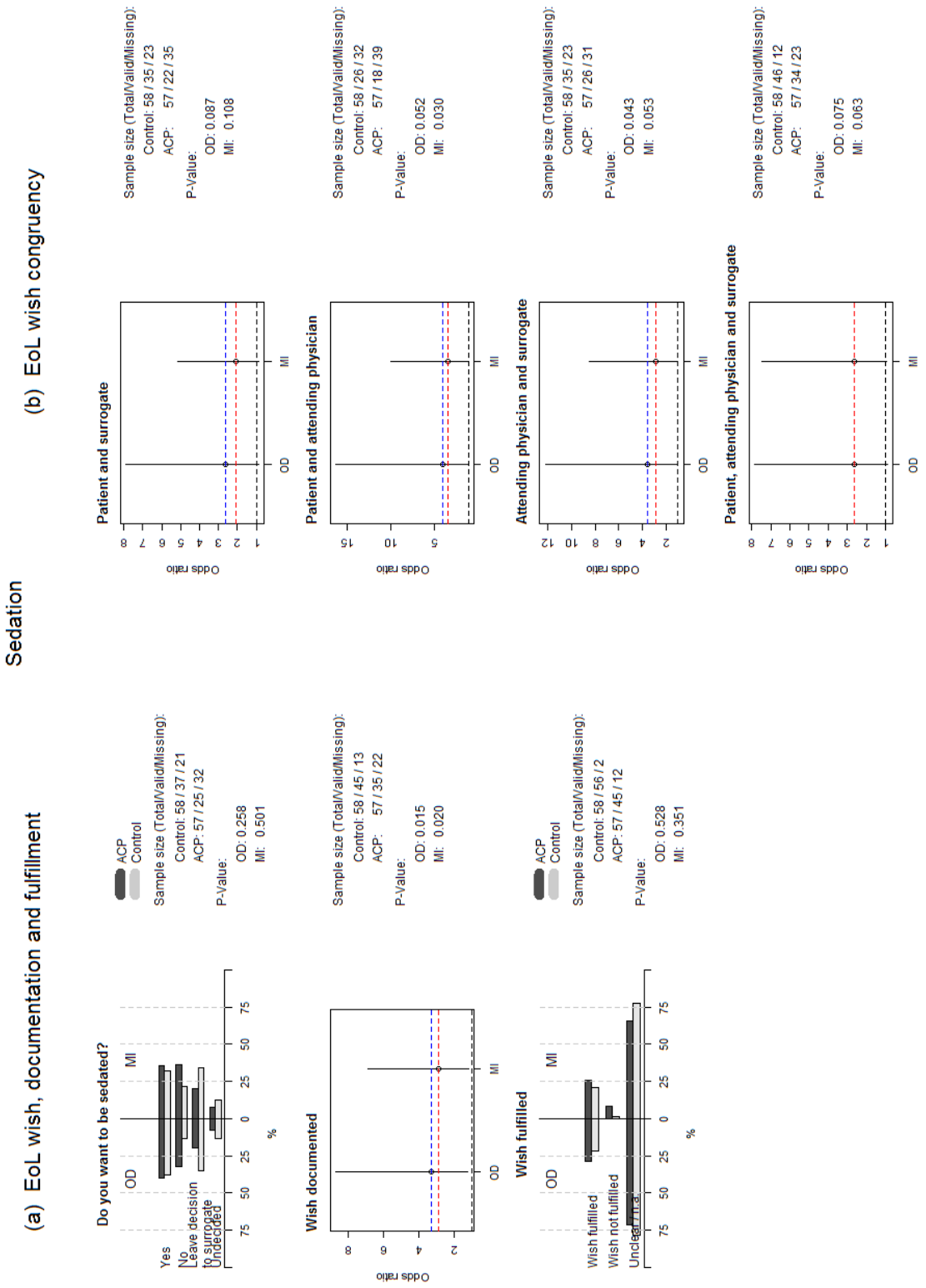
1.2.6. Last place of care



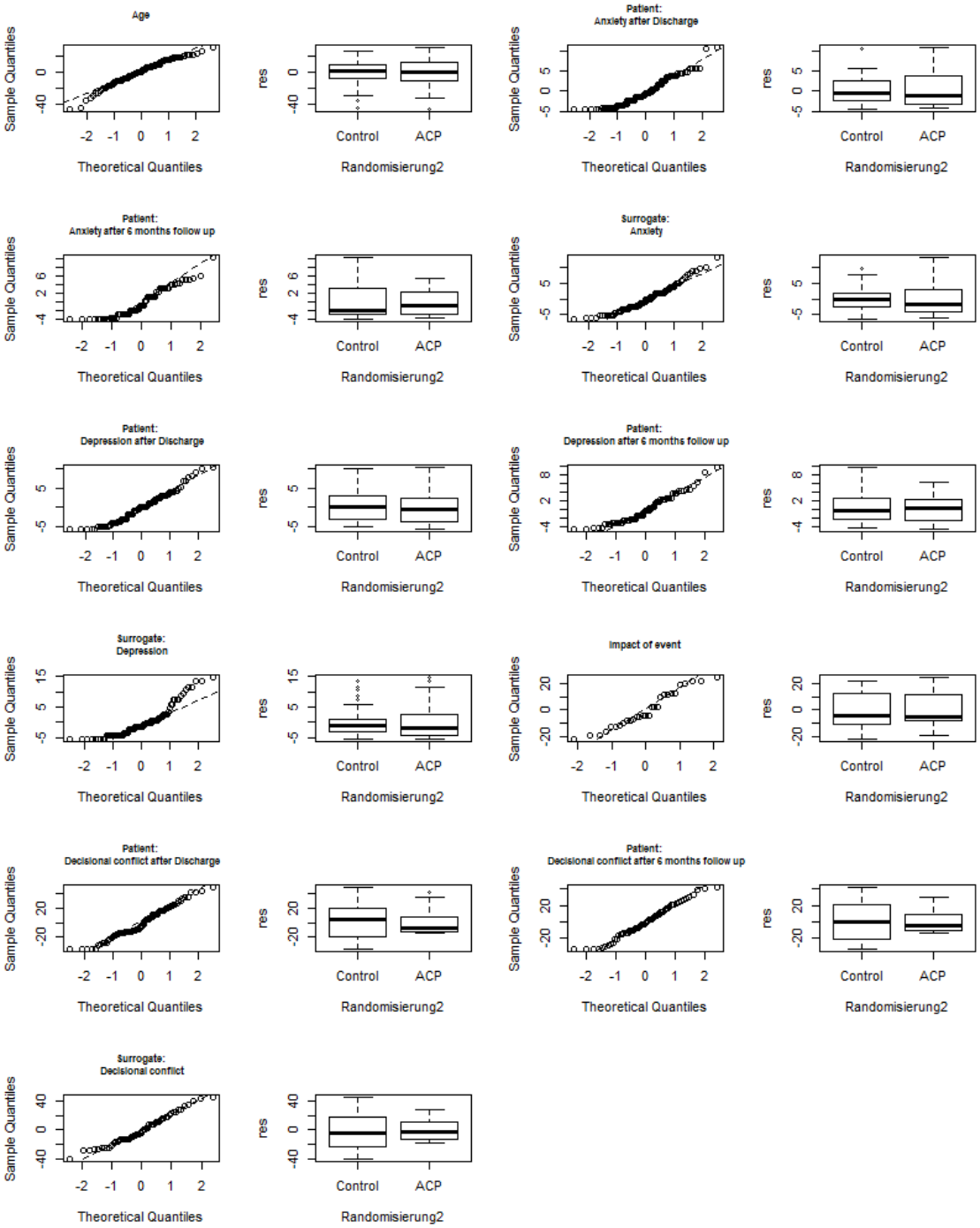
1.2.7. Resuscitation



1.2.8. Sedation



1.2.9. Residual analysis



2. Statistical methods

2.1. Categorical variables: Why not using Fisher-exact test?

For the categorical variables, the chi-square test without Yates correction was used. When the expected cell frequencies was small (less than 5), a MCMC-simulation was used. Both tests were performed with R:

```
chisq.test(data)     # classical
chisq.test(data, simulate.p.value=TRUE)   # MCMC-simulation
```

Hope, A. C. A. (1968) A simplified Monte Carlo significance test procedure. J. Roy, Statist. Soc. B 30, 582–598.
Patefield, W. M. (1981) Algorithm AS159. An efficient method of generating r x c tables with given row and column totals. Applied Statistics 30, 91–97.

2.2. Dichotomuous Variable: Why using Bayes logistic regression when there are few events?

We used classical logistic regression except when there was complete separation or one cell had less than 5 observations (arbitrarily). When this was the case, we used Bayes logistic regression in R using *bayesglm* from package arm.

Justification:

Complete separation:

Andrew Gelman, Aleks Jakulin, Maria Grazia Pittau and Yu-Sung Su. (2009). “A Weakly Informative Default Prior Distribution For Logistic And Other Regression Models.” The Annals of Applied Statistics 2 (4): 1360–1383.

Small number in cell:

Vittinghoff, E. and C.E. McCulloch (2006) “Relaxing the rule of ten events per variable in logistic and Cox regression.” American Journal of Epidemiology 165: 710-718.

Courvoisier, D.S., C. Combescure, T. Agoritsas, A. Gayet-Ageron and T.V. Perneger (2011) “Performance of logistic regression modeling: beyond the number of events per variable, the role of data structure.” Journal of Clinical Epidemiology 64: 993-1000.

2.3. Continuous variables: Why not Levene's test

To compare the mean between randomization groups we used Welch's test.

Justification:

Zimmerman, D. W. (2004), A note on preliminary tests of equality of variances. British Journal of Mathematical and Statistical Psychology, 57: 173–181. doi:10.1348/000711004849222

2.4. Pooling of Standard Errors (Rubin's Rules)

Enders, Craig K. (2010): Applied Missing Data Analysis. The Guilford Press, New York.

Page 222:

SE: Standard Errors
m: Number of imputations

Within-imputation variance V_W:

$$V_W = \frac{1}{m}\sum_{t=1}^{m} SE_t$$

Between-imputation variance V_B:

$$V_B = \frac{1}{m-1}\sum_{t=1}^{m}\left(\hat{\theta}_t - \hat{\bar{\theta}}\right)$$

Total sampling variance V_T:

$$V_T = V_W + V_{B+}\frac{V_W}{m}$$

2.5. Pooling of χ^2-statistics

van Buuren, Stef (2013): Flexible Imputation of Missing Data, Boca Raton: CRC Press.

Page: 159

Li, K.-H., Meng, X.-L., Raghunathan, T.E., and Rubin, D.B. 1991. Significance levels from repeated p-values with multiple-imputed data. Statistica Sinica, 1(1), 65-92.

1. Pool χ^2-statistics (average) $\overline{\chi^2}$:

$$\overline{\chi^2} = \frac{1}{m}\sum_{t=1}^{m}\chi_t^2$$

2. Relative increase of the variance $\overline{r_\chi}$:

$$\overline{r_\chi} = \left(1+\frac{1}{m}\right) + \frac{1}{m} + \sum_{t=1}^{m}\left(\sqrt{\chi_t^2} - \sqrt{\overline{\chi^2}}\right)^2$$

3. Compute test-statistics D_χ:

$$D_\chi = \frac{\frac{\overline{\chi^2}}{k} - \frac{m+1}{m-1}\overline{r_\chi}}{1+\overline{r_\chi}}$$

4. Compute Reiter's degree of freedom v_χ:

$$v_\chi = k^{-\frac{3}{m}}(m-1)\left(1+\frac{1}{\overline{r_\chi}}\right)$$

where k is degree of freedom from $\chi^2 - test$.

5. Compute p-value P_χ:

$$P_\chi = Pr\left[F_{k,v_\chi} > D_\chi\right]$$

2.6. Multiple imputation

1. According to the study design, most of the present missing data was due to the death of the participants during the study. Because of this outcome, we can assume that the missing data was missing at random (MAR), as the missing data was not dependent on the question itself, but on the inability of the respondent to answer. We can suppose that MAR might not be the case for the surrogates, as it can be argued that some specific questions from the outcome scales (ex. HADS) might not have been answered because of the reasons which are being assessed by the questions themselves (For example 25 surrogates did not answer the question "I still enjoy the things I used to enjoy"). In such cases, it could be argued that the data is missing not at random (MNAR). However, as surrogates that did not answer the scale questions, also failed to complete other questionnaires, this might imply that the data was missing not because of the questions themselves but because of other reasons. One possible reason could be the fact that their relative died (recorded by the variable Todesstatus).

2. Before performing MI, the data was split into two datasets: one with the control group and the second with the intervention group. This decision was taken to make sure that the imputed variables will be determined by the predictors exclusively within each group. "This is necessary in randomized trials, where interactions as yet unidentified between treatment and patient characteristics (covariates) may be present. If imputation is not done separately for each treatment group, estimates of interactions with treatment in the analysis model are biased toward zero." Royston P. Multiple imputation of missing values: further update of ice, with an emphasis on categorical variables. Stata J. 2009;9(3):466

To do this, the original dataset was split into two separate files (select cases function) which allowed to perform the multiple imputation in two separate files for the two randomized groups. After the multiple imputation was performed, the data was merged again.

3. Imputation specification:

   a. Used system: SPSS 22

   b. Number of imputations: 10

   c. Variables used in the imputation procedure: Within this study, patients wishes regarding eight end of life treatment options have been assessed: resuscitation, antibiotics, dialysis, artificial nutrition, intravenous fluids, intubation, sedation and last place of care. For the multiple imputation the following variables have been included (both as a predictor and outcome for the imputation):

      i. Eight variables that assess whether the patients' wishes was documented in the medical records

      ii. Eight variables that assess whether the patients' wishes were fulfilled

      iii. 33 variables that assess what are patients' wishes

      iv. 33 variables that assess what the surrogates believe patients' wishes are

v. 33 variables that assess what the attending physicians believe patients' wishes are

vi. One variable that assesses whether the patient has any end of life wishes

vii. One variable that assesses whether the surrogates know if the patient has any end of life wishes

viii. One variable that assesses whether the attending physicians know if the patient has any end of life wishes

ix. Seven patient demographical questions: age, gender, education, religion, religiousness, civil status, main diagnosis

x. Four screening questions: presence of frequent admissions, difficult to control symptoms, complex care requirements, decline in functioning

xi. Four baseline questions: presence of surrogate, advanced care directive, wish to be resuscitated, wish for a specific medical treatment

xii. Eight discharge questions: Presence of surrogate, advanced care directives, communication with medical workers about diagnosis and future wishes and 5 satisfaction questions (involvement of patients in the decision making, involvement of surrogates in the decision making, respect of the medical workers when discussing diagnosis and treatment, offered care, given information)

xiii. Two questions six months after the discharge: presence of surrogate, advanced care directive

xiv. Three HADS Anxiety scale (only the total sum): Sum of subscale for patients answers after discharge, six months after discharge and sum of subscales for surrogates

xv. Three HADS depression scale (only the total sum): Sum of subscale for patients answers after discharge, six months after discharge and sum of subscales for surrogates

xvi. Impact of event scale (only total sum)

xvii. Two decisional conflict scale (only total sum): discharge and six months after discharge

xviii. One decisional conflict sum (total sum)

xix. Period of the study when the patient died

xx. Place of death

xxi. 33 variables that assess the congruency between the patient and the surrogate regarding the end of life treatment options

xxii. 33 variables that assess the congruency between the patient and the attending physician regarding the end of life treatment options

xxiii. 33 variables that assess the congruency between the patient, the surrogate and the attending physician regarding the end of life treatment options

d. Used statistics: see section2.

e. Because the missing pattern was arbitrary, the MCMC (Markov chain Monte Carlo) imputation method was used

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 3-4
	2b	Specific objectives or hypotheses	Page 3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 2,3,4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page 5
Participants	4a	Eligibility criteria for participants	Page 5, Figure 1
	4b	Settings and locations where the data were collected	Page 4,5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 4,5,6; Suppl. file 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 6-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	none
Sample size	7a	How sample size was determined	Page 10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	none
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 2,4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 2,4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Page 4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 4

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 2,3,4,5
	11b	If relevant, description of the similarity of interventions	Page 5,6
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 10; Suppl file 1
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 10,12, Suppl file 1
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1; Table 3,4,5; Page 2, 11
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1 ; Table 3; Page 11,17
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 4,5,7
	14b	Why the trial ended or was stopped	Page 7
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tables 3 and 4
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 4,5,6 ; Suppl file 1 ; Figure 1 ; Page 11-16
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 5, 6; Suppl file 1; Page 12-16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 5, 6; Suppl file 1; Page 12-16
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Suppl file 1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Table 5
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 10, 16-

			19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 16-19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 16-19
Other information			
Registration	23	Registration number and name of trial registry	Page 4
Protocol	24	Where the full trial protocol can be accessed, if available	Page 4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 4

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Additional features for pragmatic trials (Zwarenstein et al. Improving the reporting of pragmatic trials: an extention of the CONSORT statement. BMJ 2006; 337)

Addition to 2 Background
Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem
Page 3-4

Addition to 3 Participants
Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems)
Page 5-6, Table 3

Addition to 4 Interventions
Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites
Describe the comparator in similar detail to the intervention
Page 4,7

Addition to 6 Chosen Outcomes
Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial
Page 7-10

Addition to 7 Sample Size
If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained
n.a.

Addition to 11 Blinding
If blinding was not done, or was not possible, explain why
Page 4-5 why blinding was possible but not regarding full observer blinding, discussion 18-19

Addition to 13 Participant flow
The number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported
Table 3, Table 4, figure 1

Addition to 21 Generalisability
Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organisation, staffing, or resources may vary from those of the trial
Page 16-20
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Krones T, *et al. BMJ Support Palliat Care* 2022;0:1–13. doi: 10.1136/bmjspcare-2017-001489