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Title: Feasibility and acceptability of conducting a partially randomised RCT examining interventions to improve psychological health after discharge from ICU

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Title: Feasibility and acceptability of conducting a partially randomised RCT examining interventions to improve psychological health after discharge from ICU

Abstract

Background:

Interventions to support psychological recovery after critical illness, including information provision via an intensive care unit (ICU) diary or discharge summary, have been widely adopted in some regions, albeit without strong empirical evidence.

Objective:

To examine the feasibility and acceptability, for patients, family members and clinicians, of information provision via an ICU diary or discharge summary to support psychological recovery for critical illness survivors.

Methods:

A pilot, partially randomized patient preference study in a mixed ICU in a tertiary hospital in Australia. Eligible patients were in ICU >24 hours and able to converse in English. Interventions were ICU Diary or Discharge Summary compared to usual care. Feasibility was assessed throughout the study process, with acceptability assessed 3 and 6 months after hospital discharge, with data analysed descriptively and thematically.

Results:

Sixty-one patients were recruited, 45 completed 3 month follow-up (74%) and 37 (61%) 6 month follow-up. Participants were medical (39%), surgical (30%) and trauma (31%) patients; age 55 [interquartile range, IQR:36-67] years; and stayed in ICU 7 [IQR:3-13] days and hospital 23 [IQR:14-32] days.

Within the partially randomised framework, 34 patients chose their intervention – 4 chose usual care, 10 ICU Diary and 20 Discharge Summary. The remaining 27 patients were randomised – 9 usual care,

10 ICU Diary and 7 Discharge Summary. The majority (>90%) considered each intervention helpful during recovery, however a significant proportion of patients reported distress associated with reading the ICU Diary (42%) or Discharge Summary (15%). Clinicians reported they were hesitant to make diary entries.

Conclusions:

When given choice, more patients chose a Discharge Summary over the ICU Diary or usual care. Participants considered both interventions acceptable. Given the reports of distress associated with information provision, clear empirical evidence is required to determine effectiveness, optimal timing, support needed and for whom they should be used.

Key words: critical care, intensive care unit, patient outcome assessment, patient information, ICU diary, discharge summary

Introduction

Psychological health after critical illness has been repeatedly identified as a problem, with approximately one third of patients reporting symptoms of anxiety ¹, depression ² and/or post-traumatic stress ³. Interventions to support psychological recovery have included visits by Intensive Care Unit (ICU) staff to patients post ICU discharge, survivors revisiting ICUs with healthcare professional support ⁴⁻⁶, counselling during the ICU admission and/or recovery period ⁷⁻⁹, and provision of information via either an ICU diary ¹⁰ or a discharge summary ¹¹. These latter two strategies have been widely adopted in some geographical regions, albeit without strong empirical evidence.

At the time of commencing this work there had been a lack of empirical work examining the efficacy of patient diaries with only two randomised controlled trials ^{12, 13} and various observational studies completed. These varied in format and timing of the diary and outcome assessment, and often had low participation suggesting many patients are either not suitable for the intervention or choose not to receive it ¹⁴. Despite these limitations, there is evidence that some patients find this format of information useful and beneficial ^{15, 16}.

The provision of discharge information to patients post ICU has also been proposed ¹⁷. Work has focused on developing information resources that are individualised to the needs identified by patients, although no evidence of benefit yet exists ^{11, 18}. There is also a lack of knowledge regarding the role of patient preference and current psychological health on benefit of information provision.

This study was designed to determine the feasibility and acceptability, from the perspective of patients, family members and clinicians, of two information-based interventions for survivors of critical illness, taking into account preferences for information provision.

Materials and Methods

A single site, pilot, repeated measures, partially randomised patient preference study was conducted to test feasibility and acceptability of the study process and interventions. Ethical approval was provided by relevant hospital and university ethics committees.

Participants

Consecutive patients expected to be in ICU for >24 hours, able to speak and understand English, had a Glasgow Coma Score of ≥ 14 prior to leaving ICU, and expected to survive >1 month beyond hospital were invited to participate. Patients were excluded if they were not able to receive the intervention or be followed up post discharge (e.g. overseas patients, prisoners, inter-hospital transfers from ICU), were < 18 years old, had no family or social support, were previously enrolled in this study (patients readmitted to ICU during the study period), had active psychotic impairment or cognitive impairment, and had suicide attempt as primary reason for ICU admission. Family members of the patients who consented to study involvement, and clinicians who contributed to the ICU diary or discharge summary, were also invited to participate.

Study process

A partially randomised patient preference process was used¹⁹. Patients were screened daily and, if considered potentially eligible for study inclusion, the patient or family was approached to seek an indication of likely participation, as well as ensure the family was prepared to contribute to a diary. This agreement needed to be received by day 4 of the patient's ICU stay at the latest to enable a Diary to be commenced soon after. A positive response led to an ICU Diary and a Discharge Summary being commenced, however neither of these were provided to the patient until after they consented to participation. Informed consent was obtained from the patient, and eligible family members, after discharge from the ICU and reconfirmed verbally at all subsequent data collection points. Five days after ICU discharge psychological screening using the Hospital Anxiety and Depression Scale (HADS)²⁰ and the Posttraumatic Stress Disorder Checklist – Civilian Version 5 (PCL-5)²¹ was conducted. Patients were allocated to study groups using a partially randomised process based on screening and patient preferences. Patients with HADS-Total ≥ 8 chose their preferred intervention. Patients with HADS-Total ≤ 7 were randomised to study groups following computer-generated random assignment using a 1:1:1 ratio with variable block sizes of 3 – 6 via an online randomisation service. Although the appropriate cut-off score for identifying distress in critical care patients has not been

clearly agreed, the cut-off was selected to maximise sensitivity as a screening tool, separating healthy individuals from the distressed, the latter subsequently having a choice in the intervention received ²². Thus ensuring that patients experiencing psychological distress were not exposed to an intervention they did not wish to receive. Patients were followed up 3 and 6 months after ICU discharge (Supplementary figure 1). Strategies to retain participants in the study included use of multiple contact details and regular and multiple attempts at communication using each participant's preferred contact method. All data were stored in a re-identifiable format with computer files password protected and hard copy in locked facilities.

Interventions

Participants either chose, or were randomly assigned to receive:

1. Usual care: no formal ICU follow-up was provided, and no specific information provision or psychological support was routinely provided to patients.
2. ICU Diary: participants received a narrative account of their ICU journey jointly documented by ICU staff and family members throughout the ICU stay. The diary was retained in ICU after patient discharge, and was provided to the participant when she/he indicated readiness to receive the diary (between 5 days and 3 months after ICU discharge). Guidelines were available for writing in the ICU diary (Supplementary File 2).
3. Discharge Summary: the ICU Research Nurse prepared a summary of the ICU experience including reason for admission, duration of ICU stay, main treatments and procedures and other relevant information based on the User Centred Critical Care Discharge Information (UCCDIP) ²³, <https://icusteps.org/professionals/discharge-information>. The summary was reviewed by an ICU Clinical Nurse Consultant, then given to participants in hospital after consenting or later as requested. At least one telephone call post hospital discharge was made to participants. Additional strategies potentially available to participants in this group included up to two discussions with a psychologist, a supported ICU visit and information outlining additional support options.

Outcomes

The outcomes assessed were feasibility (eligibility, recruitment, missing data and protocol fidelity) ²⁴, acceptability and psychological health at 3 and 6 months. Feasibility measures included: 1) proportion of patients who met eligibility criteria, were recruited and successfully followed up at each time point; 2) proportion of protocol adherence and reasons for lack of adherence; 3) proportion of, and reasons for, missing data; 4) number of entries in each ICU diary and category of author (health care team member, family member) of those entries; and 5) type and number of additional strategies requested by participants in the study group where this was possible.

Acceptability for patients and family members was assessed 3 and 6 months after ICU discharge, and from ICU staff on one occasion. Mixed methods assessment of acceptability included: 1) number and proportion of patients who chose each of the interventions when choice was possible; 2) structured questionnaires of intervention acceptability based principles outlined by Gwadry-Sridhar and colleagues ²⁵; and 3) semi-structured interviews to explore perceptions of acceptability. Patients and family member consent was confirmed prior to the interview; clinicians provided consent at the beginning of interviews. Interviews were conducted via telephone for patients and family members, and in a meeting room in the ICU for clinicians, and were audiotaped and transcribed verbatim.

Psychological health measures included the anxiety and depression sub-scales of the HADS ²⁰ and the PCL-5 ²¹. Personnel conducting follow-up were blinded to group allocation and conducted follow-up via mail, email, telephone or face-to-face.

Data analysis

Quantitative data analysis: Descriptive characteristics are presented using means and standard deviations (SDs) or medians and interquartile ranges (IQRs) for continuous variables based on normality, and percentages for categorical variables. Comparisons of the characteristics of responders and non-responders were made using Chi-square or Fisher's exact test, t-test for differences in means, and nonparametric tests for rank differences. IBM SPSS v22 (Armonk, NY, IBM Corp) was used for analysis by personnel blind to group allocation.

Qualitative content analysis: A conventional approach to content analysis of acceptability was undertaken, with interview transcripts being read multiple times, highlighting and coding text that described the participants' perceptions of acceptability of the interventions ²⁶. After open coding of four transcripts, preliminary codes were decided, and a tree diagram was developed. New codes were added when data did not fit into existing codes. The final codes from all transcripts were organised into a hierarchical structure. NVivo software in addition to hand coding was used for analysis of text data ²⁷.

Results

Eligibility, recruitment and follow-up: In total 3,782 patients were screened between June 2016 and February 2018. Five hundred and ninety-one patients were eligible for the study and just over 10% (n = 61) consented (see Table 1 for demographic and clinical information). The main reason for not recruiting eligible patients was unavailability of study personnel. A small number of families did not consent or declined diary commencement (Figure 1).

Choice of intervention: Of 34 participants who chose an intervention, 20(59%) preferred the Discharge Summary (including one person who wanted only the additional support of psychological sessions), 10(29%) preferred the ICU Diary and 4(12%) preferred usual care. Patients requested their ICU diary or Discharge Summary a median of 20 (IQR:11-36) days after ICU discharge.

Follow-up: Retention in the study was challenging with 45 (74%) of patients completing follow up at 3 months and 37 (61%) at 6 months (Figure 1), with variation from 48% (Discharge Summary group) to 80% (ICU Diary group). Reasons for declining or withdrawing in the Discharge Summary group included being "too sick", "still trying to settle at home" or "it was too much". In the usual care group participants who withdrew did not provide a reason. The only reason for missing data was loss to follow-up or withdrawal from the study.

Intervention fidelity: One participant was excluded after consent due to a protocol breach (participant given ICU Diary prior to randomization). One participant in the usual care group was excluded after being given the ICU diary to read.

Patients were in ICU 2 days [1.0-3.0] before they had their ICU Diary commenced, which was developed over 4 [2.0-10.0] days. The diaries had a total of 747 entries, representing 6 [3.0-17.0] entries per diary.

The majority of entries were from family and friends (n=577, 77%). Other contributions were from the nursing team (n=155, 21% [research nurses n=83, 11%; clinical nurses n=72, 10%]), physiotherapists (n=7, 1%), other allied health professionals (n=2, 0.3%) and other (n=5, 0.7%). Despite the invitation to contribute to the diary, other professionals (e.g. medical doctors, occupational therapists, pastoral care) did not write in the diary.

Additional strategies requested by participants: Within the study protocol, 34 participants had the opportunity to choose additional interventions. Six participants from the ICU Diary group requested the Discharge Summary after the 6-month follow up. Nine patients from the Discharge Summary group requested an ICU Diary and eight requested psychological sessions. No participants requested a supported visit to the ICU or provision of detailed information outlining additional support. Independently of the study approximately half of the patients sought out someone other than a relative or friend to discuss their ICU experience (ICU diary: 11(58%); Discharge Summary: 11(44%); Usual care: 2(20%). These discussions were usually with a psychologist, psychiatrist or general practitioner (Supplementary Table 2).

Acceptability: The majority of the patients in the ICU Diary group completed the acceptability questionnaire (n=16, 80%), and participated in the acceptability interviews (n=13, 65%). In the Discharge Summary group 17(63%) participants completed the acceptability questionnaire and 13(48%) participated in interviews. Although demographic characteristics of participants were similar, some clinical characteristics differed with patients in the ICU Diary group having higher APACHE III, requiring longer mechanical ventilation and ICU stay (Table 1). These factors could have influenced the response rate of participants.

Patients were generally positive about both interventions. In the acceptability questionnaires, most patients reported that the information contained in the ICU Diary or Discharge Summary was helpful to their recovery, and would recommend the intervention to others (Table 2). However, both groups of patients acknowledged that reading the ICU Diary or Discharge Summary caused them distress (ICU Diary: 20-42%; Discharge Summary: 15-20%) and made them more worried about their health (ICU Diary: 13-42%; Discharge Summary: 13-15%).

Eleven family members completed the acceptability questionnaires, and 9 participated in the interviews (n=6 ICU Diary, n=3 Discharge Summary). Family members' views were similar to those of patients, with most relatives agreeing the information was helpful, and would recommend the intervention to others (Supplementary Table 3). Unlike patients, no family members found reading the ICU Diary or Discharge Summary caused them distress or made them more worried about their relative's health.

During the semi-structured interviews patients, family members and clinicians raised consistent themes. They considered the ICU Diary to be helpful for recovery and for improving memory and understanding after the ICU experience. However, patients reported distress associated with reading the ICU Diary, while family members noted writing in the diary was 'overwhelming'. Some clinicians also anticipated this and expressed their concern. Family members and clinicians also questioned the suitability of ICU diaries to provide support to the patient. For example, one family member reported that it was "overwhelming to write in it" and another said "It would be terribly sad for the family to get the diary if their relative doesn't make it". A clinician questioned "Is it right for patients with a fractured family?" Other questions included the optimal time to receive the diary and who should contribute to the diary. Clinicians also raised legal concerns regarding ownership of the diary (Table 4).

Despite patients reporting distress, the Discharge Summary was also considered helpful in understanding the ICU experience and with improving memory. There were various opinions amongst patients on whether the level and depth of information was appropriate, with some patients saying "it was comprehensive...and sufficient" and others "I wanted a lot more medical information". Although family members did not report distress, one noted being apprehensive about reading the Discharge Summary, with another indicating they found the new information 'a bit of a shock'. Patients and clinicians agreed that additional support should be available for the patient when provided with the Discharge Summary as well as follow-up after discharge from ICU (Table 4).

Psychological Health

Approximately half of the patients reported symptoms of distress (HADS-T \geq 8) at baseline, with a reducing proportion reporting these symptoms over time. A similar pattern was reported in regard to

symptoms of anxiety (HADS-A \geq 8) and depression (HADS-D \geq 8), although with fewer participants experiencing symptoms (Supplementary Table 1). Only five study participants reported posttraumatic stress symptoms (PCL-5 \geq 33) at each time.

Discussion

This study was a pilot, partially randomised patient preference study with patients assigned to receive either usual care, ICU Diary or Discharge Summary. Although the feasibility of conducting a study to examine the effect of a diary intervention has been previously demonstrated^{12, 16, 28}, incorporating patient preference has not. The wish to intervene post-ICU reflects the humane desire to help, however, psychological interventions post-trauma are rarely neutral and may actually inhibit recovery²⁹. What constitutes ‘helpful’ information will vary among ICU patients based on their individual experience and their current level of distress. This study represents the first known examination of feasibility of incorporating critical care patients’ preference into an RCT¹⁹. There is growing recognition that this may be an important determinant of study feasibility³⁰ and treatment effect in other populations³¹.

Anticipated risks to participants related to potentially experiencing distress as they recalled their time in ICU and hospital. Crucially, an individual distressed while receiving information would not necessarily regret receiving that information and remembering the past, and it could aid insight and resolution³². Of note, approximately half of the participants in the intervention groups had additional conversations about their time in ICU with either their GP or a psychologist.

Recruitment and retention in the study were challenging. Although the number and complexity of patients in the study site (>1500 admissions of >24 hours annually) was anticipated, we expected to recruit participants more quickly than occurred. Only 61 participants were recruited over 21 months, with 37 completing follow-up at 6 months using standard non-monetary retention strategies^{33, 34}. Adequate resourcing of Research Nurses at all study points, and use of multiple study sites, is essential to overcome this challenge.

Despite constant encouragement, the frequency of clinicians’ contribution to ICU diaries was poor, with nurses primarily contributing to them. Nurses were also the largest group of clinicians participating in the acceptability interviews. This intervention may have been seen as a component of

nursing care, with other clinicians not seeing the diaries as relevant in their scope of practice.

Intervention fidelity and authorship of diary entries is rarely reported. In one small study the mean number of entries was 6³⁵. In contrast a recent French multi-centre study, diaries had an average of 13.5 pages of text, with 51% of diary entries written by family members, 34% by nurses and 15% by physicians²⁸, suggesting authorship challenges are not universal. Understanding views of all clinicians, and the influence of culture, is necessary.

When given the choice, more participants chose the Discharge Summary rather than the ICU Diary. In this cohort of patients, it appears that a summary containing objective information about the patient's journey through ICU was most appealing to the participants. However, patients who received the Discharge Summary had experienced shorter stays in ICU than those who received the ICU Diary (5 vs 8 days), and a greater proportion was lost to follow-up. Further exploration of preference in the context of ICU length of stay, severity of illness and study retention is warranted.

Although both the ICU Diary and Discharge Summary were seen as beneficial and helpful to recovery, a substantial minority of participants described experiencing distress as they read the information, and subsequently worried about their health. This is an important finding, and suggests appropriate support during and after receiving the information is required. It may be that both of information provision strategies should be incorporated into broader support strategies after critical illness, although the benefit and most appropriate format for such support remains unknown^{36, 37}.

This is the first study to explore multiple stakeholders' perceptions of acceptability of receiving information via either an ICU Diary or Discharge Summary after a critical illness. Study results should be interpreted as pilot data, noting the small sample size and attrition rate, and should be used to inform larger multi-centre studies to investigate information provision after critical illness. Further, in order to make participation as flexible as possible, follow-up interviews were conducted via telephone, mail/email or in person – whether data collected using all these methods is equal is unknown.

In conclusion, when given choice, more patients chose a Discharge Summary, rather than an ICU Diary, to receive information about their critical illness. Delivery of both interventions within a randomised trial was feasible, as was incorporation of patient preference. Although recruitment and retention rates were low, those patients who did participate considered both interventions acceptable. The potential for

patients to experience distress with either intervention is highlighted. It is likely only a proportion of ICU patients require, or would benefit from, an intervention. Who should receive information, as well as the nature and timing of information and associated support, need to be defined empirically.

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Ethical approval and consent to participate

The Griffith University (EC00162), The University of Queensland (EC00456) and Metro South (EC00167) Human Research Ethics Committees approved this study. Informed consent was obtained from the patients and eligible family members after discharge from ICU and reconfirmed verbally at subsequent data collection points.

Figure Legends

1. Figure 1. Participants flow through study
2. Table 1. Demographic and clinical characteristics of participants
3. Table 2. Patient acceptability questionnaire of the ICU Diary and Discharge Summary at 3 (n=12 and n=13) and 6 (n=15 and n=15) month follow-up
4. Table 3. Stakeholders' views about ICU Diaries
5. Table 4. Stakeholders' views about Discharge Summaries
6. Supplementary Figure 1. Study process
7. Supplementary File 2. Guidelines for preparing the ICU diary
8. Supplementary Table 1. Sedation and analgesia during ICU treatment
9. Supplementary Table 2. Additional discussions about ICU experience

10. Supplementary Table 3. Family member acceptability questionnaire of ICU Diary and Discharge Summary at 3 (n=3 and n=0) and 6 (n=5 and n=4) month follow-up
11. Supplementary Table 4. ICU patients' psychological health at baseline, 3- and 6- months by treatment group

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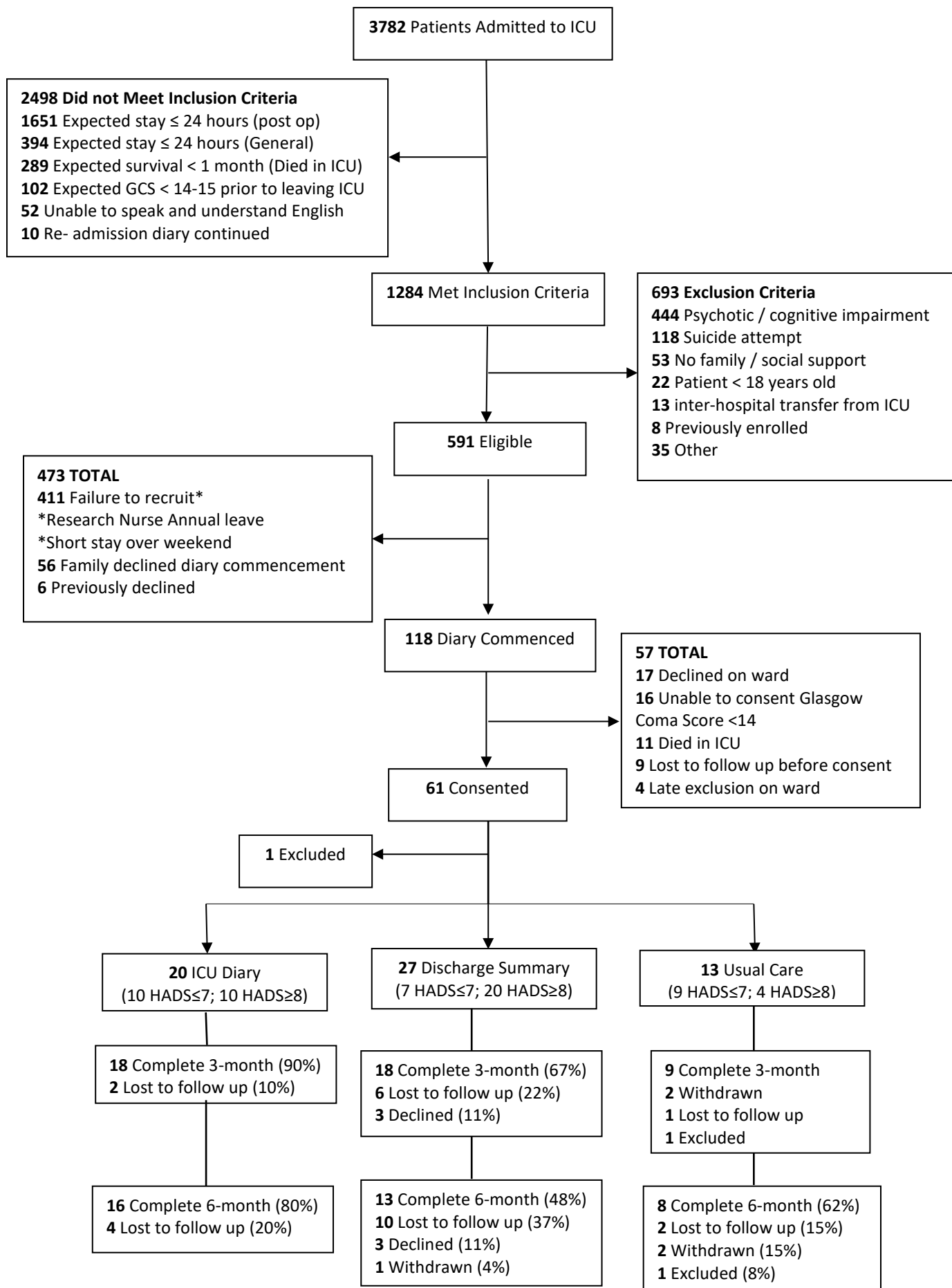


Figure 1 Participants flow through study

Table 1: Demographic and clinical characteristics of participants

Characteristic	ICU Diary (n=20) Frequency (percentage)	Discharge Summary (n=27) Frequency (percentage)	Usual Care (n=13) Frequency (percentage)
Gender			
Male	13 (65.0)	19 (70.4)	9 (69.2)
Female	7 (35.0)	8 (29.6)	4 (30.8)
Age (years) median (IQR)	56 (39.5-69.5)	57 (35.0-67.0)	52.0 (27.5-59.5)
Ever visited HCP for psychological condition prior to ICU admission – yes	12 (63)	9 (36)	3 (30)
Reason for ICU admission			
Medical	9 (45.0)	13 (48.1)	2 (15.4)
Surgical elective	1 (5.0)	0 (0.0)	0 (0.0)
Surgical cardiac	2 (10.0)	0 (0.0)	1 (7.7)
Surgical emergency	2 (10.0)	6 (22.2)	6 (46.1)
Trauma	6 (30.0)	8 (29.7)	4 (30.8)
Mechanical ventilation			
No	2 (10.0)	3 (11.1)	0 (0.0)
Non-invasive	1 (5.0)	0 (0.0)	0 (0.0)
Invasive	17 (85.0)	24 (88.9)	13 (100.0)
Pain (CPOT > 2)			
Yes	16 (84.2)	19 (73.1)	11 (84.6)
No	3 (15.8)	7 (26.9)	2 (15.4)
Delirium (CAM-ICU ≥ 2 times/day)			
Yes	1 (5.0)	6 (22.2)	1 (7.7)
No	19 (95.0)	21 (77.8)	12 (92.3)
APACHE III median (IQR)	77.0 (45.0-94.2)	53.0 (39.0-72.0)	55.0 (35.0-67.0)
ICU length of stay days median (IQR)	7.8 (3.0-11.5)	4.6 (2.4-12.7)	7.0 (2.8-14.2)
Hospital length of stay days median (IQR)	21.7 (13.9-34.3)	22.9 (16.4-30.5)	14.9 (11.9-30.6)
Length of invasive mechanical ventilation hours median (IQR)	129.3 (43.1-201.2)	57.6 (31.3-222.3)	131.2 (37.9-231.3)

APACHE: Acute Physiology Age Chronic Health Evaluation; CAM-ICU: Confusion Assessment Method – ICU; CPOT: Critical-care Pain Observation Tool; HCP: health care professional; ICU: intensive care unit; IQR: interquartile range; GP=general practitioner

Where total group numbers are not 20 or 27 or 13 data are missing/non-response from participant.

Table 2. Patient acceptability questionnaire of the ICU Diary and Discharge Summary at 3 (n=12 and n=13) and 6 (n=15 and n=15) month follow-up

ICU Diary		Strongly Disagree n (%)	Disagree n (%)	Neither n (%)	Agree n (%)	Strongly Agree n (%)
The information in my ICU diary helped me better understand my time in ICU	3 mths			1 (8)	6 (50)	5 (42)
	6 mths		1 (7)		8 (53)	6 (40)
I found my ICU diary to reflect my experience in the ICU	3 mths			3 (25)	4 (33)	5 (42)
	6 mths		1 (7)	1 (7)	7 (47)	6 (40)
I was able to easily read and understand what was written in my ICU diary	3 mths				6 (50)	6 (50)
	6 mths				9 (60)	6 (40)
The language used to write my ICU diary was at a level I could understand	3 mths				5 (42)	7 (58)
	6 mths		1 (7)		8 (53)	6 (40)
Reading my ICU diary caused me distress	3 mths	2 (17)	4 (33)	1 (8)	4 (33)	1 (8)
	6 mths	5 (33)	6 (40)	1 (7)	3 (20)	
My ICU diary provided me with a lot of information clearly and in a few words	3 mths		1 (8)		7 (58)	4 (33)
	6 mths		2 (13)	2 (13)	8 (53)	3 (20)
Reading my ICU diary made me more worried about my health	3 mths	2 (17)	5 (42)		5 (42)	
	6 mths	2 (13)	8 (53)	3 (20)		2 (13)
I would recommend the use of ICU diaries for other ICU patients	3 mths	1 (8)			2 (17)	9 (75)
	6 mths				6 (40)	9 (60)
Discharge Summary						
The information in my Discharge Summary helped me better understand my time in ICU	3 mths		1 (8)		5 (39)	7 (54)
	6 mths	1 (7)			8 (53)	6 (40)
I found my Discharge Summary to reflect my experience in the ICU	3 mths		1 (8)	1 (8)	6 (46)	5 (39)
	6 mths			5 (33)	7 (47)	3 (20)
I was able to easily read and understand what was written in my Discharge Summary	3 mths				6 (46)	7 (54)
	6 mths		2 (13)		6 (40)	7 (47)
The language used to write my Discharge Summary was at a level I could understand	3 mths			2 (15)	4 (31)	7 (54)
	6 mths		2 (13)		7 (47)	6 (40)
Reading my Discharge Summary caused me distress	3 mths	6 (46)	5 (38)		2 (15)	
	6 mths	5 (33)	7 (47)		2 (13)	1 (7)

My Discharge Summary provided me with a lot of information clearly and in a few words	3 mths	1 (8)		5 (39)	7 (54)
	6 mths	1 (7)	1 (7)	6 (40)	7 (47)
Reading my Discharge Summary made me more worried about my health	3 mths	4 (31)	7 (54)	2 (15)	
	6 mths	4 (27)	9 (60)	2 (13)	
I would recommend the use of Discharge Summaries for other ICU patients	3 mths	1 (8)		4 (31)	8 (62)
	6 mths			7 (47)	8 (53)

Table 3. Stakeholders' views about ICU Diaries

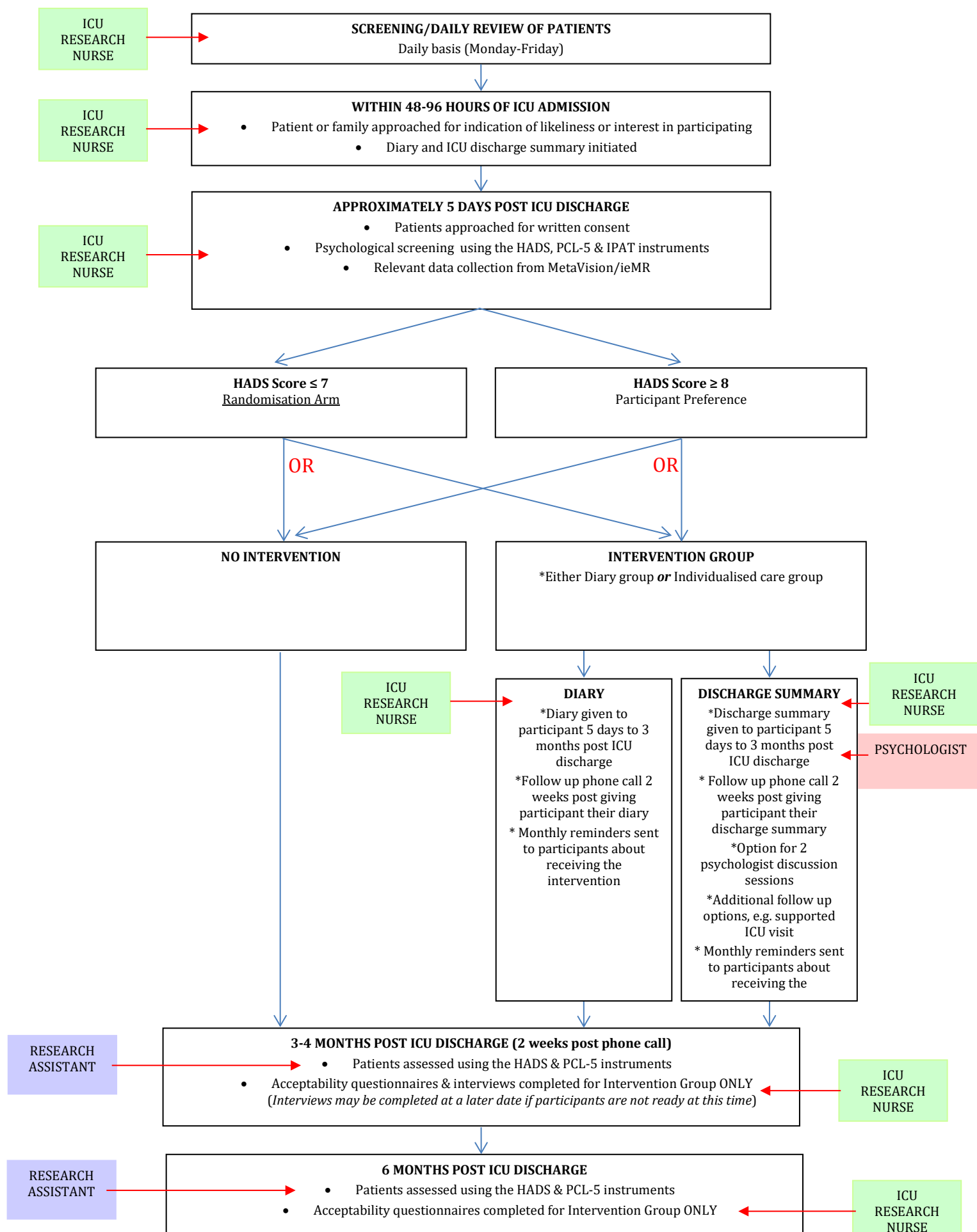
ICU Diaries			
Themes	Patients n= 13	Family n= 6	Clinicians n= 9
Helpful for recovery	It could be of value down the track Influenced my recovery a lot I don't think it influenced my recovery I had a bit of a laugh Overwhelming and heartfelt I would recommend it	Felt supported and not alone	Useful for patient and family
Improved memory and understanding	A picture is worth a thousand words [even though we didn't include pictures] Helped with memory It gave me a good understanding of my time in there It didn't make sense, I was confused	Helped with memory	Can help with memory
Distress and concern	I was worried about it. I wasn't sure what was going to be in it It was distressing to read I wasn't really keen on reading it	It took a while for the patient to want to read it	Potential anxiety and traumatic experience for patients if they remember actual procedures
Is it the right support?		Overwhelming to write in it Not sure if achievable It would be terribly sad for the family to get the diary if their relative doesn't make it	Is it right for patients with fractured family? Patient's need to be able to read, comprehend and interpret
No single right time to receive it	Diary should stay with you all the way		Time to receive it – varied from one week after ICU discharge to many weeks Need the right people to give support and explanation when the patient receives the diary
Legal concerns			Legal concerns/need to be careful Family felt it was their property

Who contributes?	It would be better if staff wrote more down More medical information	Clinicians should do more	Would be great if they became part of every day practice; needs prompts to remind us More important for families [than clinicians] to contribute Not having the time to fill it out; we should find the time to write in the diaries All members of the team could contribute
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Table 4. Stakeholders' views about Discharge Summaries

Discharge Summaries			
Themes	Patients n= 13	Family n= 3	Clinicians n= 9
Helpful to understand	<p>It was good to tell me what actually happened</p> <p>It was beneficial</p> <p>It didn't help recovery but did help my memory of what actually happened</p> <p>It gave me some optimism</p> <p>I get to understand</p> <p>I'd recommend it</p>	<p>It helped him understand what actually happened</p> <p>I'd strongly recommend it</p> <p>It provided a good overview of what happened and clarified things to me</p>	<p>Helped with memory</p>
Distress (or lack of)	<p>It was fairly helpful but a little worrying</p> <p>Pleasant to read, enjoyable and useful</p> <p>I left it for a while before I read it</p> <p>I found it distressful / I didn't find it distressful</p> <p>When I read it I was pretty emotional</p>	<p>I was apprehensive to read it</p> <p>New information was a bit of a shock</p> <p>He chose not to read it until he felt that he was ready</p> <p>Important to prepare the person for the impact that it could have as you read it</p>	
Level and depth of information	<p>Layman's terms good for most, just not for me</p> <p>Accessible language</p> <p>Some of the procedures, medical terminology was a little bit hard for me to get my head around</p> <p>It was a comprehensive; it was quite detailed; it was sufficient for what I needed</p> <p>I wanted a lot more medical information in there</p>		<p>Personality may influence patients' preferences between ICU discharge summary and ICU diary</p> <p>The language is good</p> <p>Because it's so broad there might have been particular things that a diary would have fulfilled a bit better</p> <p>Timing to give discharge summary to patients depends on patients' progress</p>

Additional support	<p>More rewarding if discussed the contents [with a health care professional]</p> <p>If they had someone they could talk to [for emotional support]</p>	<p>Going through the discharge summary with the patient and follow up either by phone or face-to-face</p> <p>Have a clinical psychologist in the ICU for patients, family and clinicians</p> <p>More standard follow-up for patients after ICU – with referral processes</p>
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Supplementary Figure 1: Study process

Supplementary Table 1: Sedation and analgesia during ICU treatment

Medications	ICU Diary (n=20) Frequency (percentage)	Discharge Summary (n=27) Frequency (percentage)	Usual Care (n=13) Frequency (percentage)
Propofol			
Yes	17 (85.0)	23 (85.2)	13 (100.0)
No	3 (15.0)	4 (14.8)	0 (0.0)
Benzodiazepines			
Yes	14 (70.0)	17 (63.0)	10 (76.9)
No	6 (30.0)	10 (37.0)	3 (23.1)
Antipsychotics			
Yes	10 (50.0)	9 (33.3)	6 (46.2)
No	10 (50.0)	18 (66.7)	7 (53.8)
Sedation-paralysis			
Yes	7 (35.0)	18 (66.7)	8 (61.5)
No	13 (65.0)	9 (33.3)	5 (38.5)
Analgesia-opioid			
Yes	20 (100.0)	26 (96.3)	13 (100.0)
No	0 (0.0)	1 (3.7)	0 (0.0)
Analgesia-non opioid			
Yes	20 (100.0)	23 (85.2)	10 (76.9)
No	0 (0.0)	4 (14.8)	3 (23.1)

Supplementary Table 2: Additional discussions about ICU experience

		ICU Diary (n=20) Frequency (percentage)	Discharge Summary (n=27) Frequency (percentage)	Usual Care (n=13) Frequency (percentage)
Since your ICU admission, have you sought out someone other than a relative or close friend to speak to about your ICU experience?				
	Yes	11 (58)	11 (44)	2 (20)
	No	8 (42)	14 (56)	8 (80)
If yes, whom did you follow up with?				
	Psychologist/Psychiatrist	7 (78)	3 (27)	1 (50)
	General Practitioner/Doctor	0 (0)	5 (46)	1 (50)
	Other	2 (22)	3 (27)	-
If yes, who was behind your decision to speak to someone?				
	Yourself	6 (67)	6 (60)	2 (100)
	Suggestion by Family member	0 (0)	1 (10)	-
	Suggestion by Hospital Staff	3 (34)	3 (30)	-

ICU=intensive care unit; IQR= interquartile range; SD=standard deviation; GP=general practitioner
 In some instances, total numbers are not 20 or 27 or 13 per group because of missing data.

Supplementary Table 3. Family member acceptability questionnaire of ICU Diary and Discharge Summary at 3 (n=3 and n=0) and 6 (n=5 and n=4) month follow-up

ICU Diary		Strongly Disagree n (%)	Disagree n (%)	Neither n (%)	Agree n (%)	Strongly Agree n (%)
The information in the ICU diary helped me to better understand my relative's time in ICU	3 mths				1 (33)	2 (67)
	6 mths		2 (40)		2 (40)	1 (20)
I found the ICU diary to reflect my relative's experience in the ICU	3 mths				2 (67)	1 (33)
	6 mths	1 (20)	1 (20)		2 (40.0)	1 (20.0)
I was able to easily read and understand what was written in my relative's ICU diary	3 mths				1 (33)	2 (67)
	6 mths			1 (20)	2 (40)	2 (40)
The language used to write my relative's ICU diary was at a level I could understand	3 mths				1 (33)	2 (67)
	6 mths				4 (80)	1 (20)
Reading my relative's ICU diary caused me distress	3 mths	2 (67)	1 (33)			
	6 mths	3 (60)	2 (40)			
My relative's ICU diary provided me with a lot of information clearly and in a few words	3 mths			1 (33)	2 (67)	
	6 mths	2 (40)			6 (60)	
Reading the ICU diary made me more worried about my relative's health	3 mths	2 (67)	1 (33)			
	6 mths	4 (80)	1 (20)			
I would recommend the use of ICU diaries for other ICU patients	3 mths					3 (100)
	6 mths				1 (20)	4 (80)
Discharge Summary						
The information in the Discharge Summary helped me to better understand my relative's time in ICU	3 mths					
	6 mths				2 (50)	2 (50)
I found the Discharge Summary to reflect my relative's experience in the ICU	3 mths					
	6 mths				2 (50)	2 (50)
I was able to easily read and understand what was written in my relative's Discharge Summary	3 mths					
	6 mths				3 (75)	1 (25)
The language used to write my relative's Discharge Summary was at a level I could understand	3 mths					
	6 mths				3 (75)	1 (25)
Reading my relative's Discharge Summary caused me distress	3 mths					
	6 mths	1 (25)	3 (75)			

My relative's Discharge Summary provided me with a lot of information clearly and in a few words	3 mths			
	6 mths		3 (75)	1 (25)
Reading the Discharge Summary made me more worried about my relative's health	3 mths			
	6 mths	2 (50)	2 (50)	
I would recommend the use of Discharge Summaries for other ICU patients	3 mths			
	6 mths		1 (25)	3 (75)

Supplementary Table 4: ICU patients' psychological health at baseline, 3- and 6- months by treatment group

	ICU Diary n=20 Median [IQR] n (%)	Discharge Summary n=27 Median [IQR] n (%)	Usual Care n=13 Median [IQR] n (%)
PCL – 5	6.6 [5.0 – 14.5]	15.0 [5.0 – 21.0]	5.0 [4.5 – 7.5]
PCL-5 \geq 33	1 (5)	4 (14)	0 (0)
PCL-5 < 33	19 (95)	23 (85)	13 (100)
HADS-Total	8.0 [3.3 – 12.8]	11.0 [7.0 – 18.0]	6.0 [2.0 – 8.0]
HADS-T \geq 8	10 (50)	20 (74)	4 (31)
HADS-T < 8	10 (50)	7 (26)	9 (69)
HADS-Anxiety	2.5 [1.0 – 6.0]	6.0 [4.0 – 10.0]	4.0 [1.0 – 5.5]
HADS-A \geq 8	4 (20)	11 (41)	2 (15)
HADS-A < 8	16 (80)	16 (59)	11 (85)
HADS-Depression	3.5 [1.3 – 6.0]	5.0 [1.0 – 8.0]	1.0 [0.5 – 4.5]
HADS-D \geq 8	2 (10)	10 (37)	0 (0)
HADS-D < 8	18 (90)	17 (63)	13 (100)
3 month follow-up	n=18 (90)	n=18 (67)	n=9 (69)
PCL – 5	10.0 [6.8– 14.8]	14.5 [8.8 – 31.3]	4.0 [2.0 – 15.5]
PCL-5 \geq 33	1 (6)	4 (22)	0 (0)
PCL-5 < 33	17 (94)	14 (78)	9 (100)
HADS-Total	9.0 [5.5 – 10.5]	7.5 [4.8 – 16.2]	4.0 [2.0 – 11.5]
HADS-T \geq 8	10 (56)	9 (50)	3 (33)
HADS-T < 8	8 (44)	9 (50)	6 (67)
HADS-Anxiety	4.5 [2.8 – 7.0]	4.5 [3.0 – 8.0]	2.0 [0.0 – 5.0]
HADS-A \geq 8	3 (17)	6 (33)	1 (11)
HADS-A < 8	15 (83)	12 (67)	8 (89)
HADS-Depression	3.5 [1.0 – 5.8]	3.0 [2.0 – 8.0]	2.0 [1.5 – 6.0]
HADS-D \geq 8	4 (22)	4 (22)	0 (0)
HADS-D < 8	14 (78)	14 (78)	9 (100)
6 month follow-up	n=16 (80)	n=13 (48)	n=8 (62)
PCL – 5	10.5 [6.0 – 20.3]	9.0 [6.0 – 28.0]	4.0 [1.3 – 25.8]
PCL-5 \geq 33	1 (6)	3 (23)	1 (12)
PCL-5 < 33	15 (94)	10 (77)	7 (88)
HADS-Total	6.5 [3.3 – 12.3]	9.0 [4.0 – 17.0]	3.5 [2.0 – 14.0]
HADS-T \geq 8	7 (44)	5 (39)	3 (38)
HADS-T < 8	9 (56)	8 (61)	5 (62)

HADS-Anxiety	3.5 [2.0 – 6.0]	6.0 [2.5 – 9.0]	1.0 [0.0 – 4.5]
HADS-A \geq 8	2 (12)	4 (31)	1 (12)
HADS-A < 8	14 (88)	9 (69)	7 (88)
HADS-Depression	2.5 [2.0 – 6.8]	3.0 [2.0 – 8.5]	3.5 [0.5 – 6.5]
HADS-D \geq 8	3 (19)	4 (31)	1 (12)
HADS-D < 8	13 (81)	9 (69)	7 (88)

Supplementary File 2: Guidelines for preparing the ICU diary

1. All members of the ICU clinical team and visitors to the patient can contribute to the diary
2. Diary content should be written in lay language
3. Photographs will not be included in the diary
4. Content may include elements of care and milestones, family activities, societal events likely to be of interest to the participant (e.g. sport, politics)

