

Timing of Exposure to ICU Diaries and Its Impact on Mental Health, Memories, and Quality of Life: A Double-Blind Randomized Control Trial

OBJECTIVES: Optimal time for ICU diary delivery and impact on mental health (MH), anxiety-depression, post-traumatic stress symptoms (PTSS), quality of life (QOL), and memories is unclear. We evaluated the effect of ICU diaries, dispatched at different time points, on outcomes in an Indian cohort.

DESIGN: Double-blind randomized controlled trial.

SETTING: A 1,000-bedded teaching hospital in East India.

PATIENTS: Mechanically ventilated (>24 hr) adults were recruited, excluding those dead or incapable of meaningful-communication at discharge or follow-up. Eighty-three patients, aged 46.2 ± 17.2 years, Acute Physiology and Chronic Health Evaluation II scores 13.7 ± 4.9 were assessed. Length of ICU stay was 8.2 ± 7.1 days with 3.7 ± 3.2 ventilator days.

INTERVENTION: Of 820 screened, 164 had diaries created. Including photographs, diaries were maintained by healthcare workers and family members. Ninety patients were randomized at 1-month follow-up: diary sent to 45 at 1 month (group ID1) and to 45 at 3 months (ID3).

MEASUREMENTS AND MAIN RESULTS: Anxiety-depression, memory, and QOL were assessed telephonically or home visits by a psychologist using the Hospital Anxiety-Depression Scale (HADS) and other tools at ICU discharge, 1-month (prerandomization), and 3 months of discharge. ID3 was reassessed after receiving diaries at 3.5 months. Primary outcome was anxiety-depression; secondary outcomes included PTSS, QOL, and memories. There was 100% follow-up. At 3 months, ID1 patients had a significant ($p < 0.001$) reduction in HADS from baseline when compared with ID3 that had not received diaries (4.16 ± 2.9 vs 2.15 ± 1.8 ; 95% CI, 2.8–1.2). PTSS scores were likewise better ($p < 0.001$). ID3 patients demonstrated significant improvement ($p < 0.01$) in QOL and memories along with HADS and PTSS when assessed at 3.5 months.

CONCLUSIONS: ICU diaries improve MH but not QOL when delivered at 1 month and assessed 2 months thereafter. Assessed after 15 days, delayed exposure at 3 months significantly improved QOL and memories in addition to MH.

KEY WORDS: anxiety; depression; diary; India; intensive care units; psychologic stress; quality of life; traumatic stress disorders

Post intensive care syndrome refers to a broad range of symptoms experienced by patients surviving an episode of critical illness (1). Essential components are psychologic, such as post-traumatic stress symptoms (PTSS), anxiety, and depression, which affect patients' quality of life (QOL), sometimes long after discharge from the ICU (2, 3).

Different types of memories and gaps in memories of ICU stay have been associated with worse QOL and mental health (MH) outcomes (4, 5). An ICU diary is an event-log of sorts maintained by healthcare workers and patient

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families to provide a lucid narrative of the sequence of events in ICU. These diaries may aid in filling gaps in memory, contextualize delusional memories, and help patients cope with their illness (6–8).

There is little data on post-ICU MH outcomes from low-middle-income countries (LMICs). A recent meta-analysis looking at the benefits of ICU diaries on patient outcome could include only eight studies (three randomized trials), all from developed high-income countries in Europe or North America (9). The studies had limitations in patient selection, time of dispatch of ICU diary, users' acceptance of the diary, and high dropout rates.

Over the last years, we have studied MH outcomes among our ICU patients and identified risk factors for worse outcomes (10). Having found an association of gaps in ICU memories, MH, and QOL (11), we began an ICU diary initiative on the unit that users received well (12).

We hypothesized that ICU diaries could improve outcomes in our population, notwithstanding the sociocultural differences from previously studied populations, and that the timing of diary dispatch and outcome assessment could potentially impact the outcomes of interest. This study was, thus, undertaken to study the effect of ICU diaries on anxiety- depression (primary outcome), PTSS, QOL, and ICU memories (secondary outcomes) in our patients.

MATERIALS AND METHODS

This randomized controlled trial (RCT) was undertaken in a 1,000-bedded tertiary-care University hospital in Eastern India. The recruitment spanned 12 months from August 2018 to July 2019, and the final follow-up was until October 2019. The trial was approved by the institute ethics committee by the ethics committee of AIIMS Bhubaneswar (IEC/AIIMS/2013/11/07/03) and registered prospectively (CTRI/2018/07/014926; Registered on: July 18, 2018). All capacious patients or their relatives (until patients became capable) signed a written consent form. The study has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Study Site

Ours is a 25-bedded mixed medical-surgical ICU. It is staffed by certified intensivists and two postgraduate critical care trainees at any point in time. The nurse-to-patient ratio is 1: 2–3. In the 2 years leading to this

study, we have mapped the prevalence of MH disorders in our population in an observational study and analyzed the effect of memories and gaps in memories on their QOL and MH outcomes (11).

Inclusion and Exclusion Criteria

We included all adult patients who were mechanically ventilated for more than 24 hours and were expected to survive ICU discharge. Death or inability to communicate meaningfully at discharge from ICU or during follow-up resulted in exclusion. Readmission to the ICU within the same hospital stay was treated as a single event.

The ICU Diary

ICU diaries had been implemented on the unit by April 2018 after a series of meetings and training for all ICU stakeholders, including doctors, nursing, and ancillary staff. Iterative changes had been made to the design after the first five diaries incorporating feedback from all users, including patient relatives. It was made of colorful paper, written in multicolored pens, and decorated with pictorial cutouts. Each diary had a “Get to know me” sheet to let the treating team know more about the patient's nickname, likes, and dislikes. An infographic page with photographs of standard ICU equipment and procedures mentioned in each diary was appreciated and accepted by the family members, helping break the ice and improve communication (12).

Initiating the ICU Diary

The clinical psychologist initiated the diary once a patient met inclusion criteria. The doctor made the first entry explaining the disease and patient status in simple language, followed by the nursing team and trainees' entries. All entries in English were transcribed into Odia, the local language, by the psychologist. The family members were shown (and read out to if needed) the initial entries and photographs and encouraged to begin writing when they felt able to.

Randomization, Allocation Concealment, and Patient Follow-Up

After ICU discharge, the diaries were kept in individually sealed envelopes with the patient's ID marked. After the assessment interview at 30 days of ICU discharge, patients were randomized into two groups by S.T.—ID1

group received the diary immediately after randomization, and the ID3 group received the ICU diary after the three months' assessment interview. A computer-generated random number sequence was used for randomization. The diaries were dispatched by trackable registered postage the day after the interview (1 mo for ID1 and 3 mo for ID3). The nurses, doctors, and family members who wrote in the diaries along with the data analyzer were blind to the group allotment.

Given the hospital's considerably wide drainage area, it was anticipated that some diaries might not reach the patients or get mislaid. In the case of delay or returned diaries, the patient would continue in the same group if the delay was within 3 weeks or be moved to ID3 by withholding diary dispatch till after the second interview at 3 months. ST handled the postal dispatch and family follow-up to ensure that the diary had reached the family as intended. The patient and family were instructed not to disclose status of diary-receipt to the psychologist at the 3-month interview. All interviews were done by the same clinical psychologist who was blind to the ICU diary group allocation of the patient. An interview guide was followed.

Data Collection and Questionnaires

The team collected clinical variables during the ICU stay, including the reason for ICU admission, length of ICU stay, duration of mechanical ventilation, administration of corticosteroids, analgesics, paralytics, and sedative drugs, pain, sedation, and delirium scores. We recorded medical history, including current substance abuse, prior/existing mental illness, previous admission to the ICU, and exposure to stressful life-threatening events such as abuse, natural disaster, and accident. Demographic details such as education, employment status, and having young children (less than 18 yr) were collected. Acute Physiology and Chronic Health Evaluation (APACHE) II score (13), Sequential Organ Failure Assessment score (14), Charlson comorbidity index (15), and Richmond Agitation Sedation Score (16) were recorded for each patient.

Patient interviews (on days 0, 30 [1 mo], 90 [3 mo], and 115 [3.5 mo]) were conducted mainly over the telephone or during follow-up at the hospital. All patients were visited at least once at home. None of the patients had only face-to-face or only-telephone interviews. An audio-recording aided the assessments to improve data capture. The Hospital Anxiety and Depression Scale (HADS) (17), the Impact of Events Revised (18),

European Quality of Life 5 Dimensions 3 levels (19), and the ICU memory tool (20) were administered at the predetermined intervals. All these questionnaires and instruments have been validated in ICU patients, including our population (10, 20).

The sample size was decided from our previous results (10). Considering a probability of type 1 error of 0.05 and 80% power, we needed 82 patients to detect a clinically meaningful drop in mean HADS scores by 35% in the group receiving the ICU diary. Counting for deaths and loss to follow-up, we needed to recruit 120 patients.

Statistical analysis was done with the SPSS Version 25 software (IBM SPSS Statistics for Windows, Version 25.0., Armonk, NY, IBM Corp.). The biostatistics experts from the institute were consulted as required for data analysis and validation. Descriptive reporting of demographic and ICU baseline data and chi-square or *t* test (or nonparametric tests as required) was done to compare the two groups. Unpaired and paired *t* tests were used to compare the difference in scores to assess MH, QOL, and memories between the groups and within-group, respectively. Both "as treated" and intention to treat (ITT) analyses were planned.

RESULTS

Of the 820 patients screened for eligibility, 201 satisfied the inclusion criteria, and ICU diaries were initiated for 164 patients. Among them, 90 were randomized, 45 in each group. In the ID1 group who received their diaries after the first assessment at 1 month, 43 completed their 3-month follow-up. After the 3-month assessment, diaries were sent to 41 patient ID3 group, and among them, 40 were followed up after 15 days of receiving the diary. The flow of patients in the study is detailed in **Figure 1**.

Protocol Violation

The "Fani," a rare severe summer cyclone, hit the state on May 3, 2019. It created acute devastation and disrupted power supply and essential services for weeks (21). Four patients in ID1 did not receive diaries on time due to postal disruption and were counted as "ID3" in the "as-treated" analysis. Two patients in ID3 received their diaries before the scheduled interview as telephonic contact was disturbed—they were considered the "ICU diary" group in the "as-treated analysis." Further results presented are for the "as-treated

analysis”; corresponding tables for the ITT analysis are presented in the supplements—both analyses yielded similar results (**Supplement Table A**, <http://links.lww.com/CCX/B36>).

Patient Characteristics

Of the recruited patients, 49 were males with a mean age of 47 ± 17 years. Most of them ($n = 69$) were educated

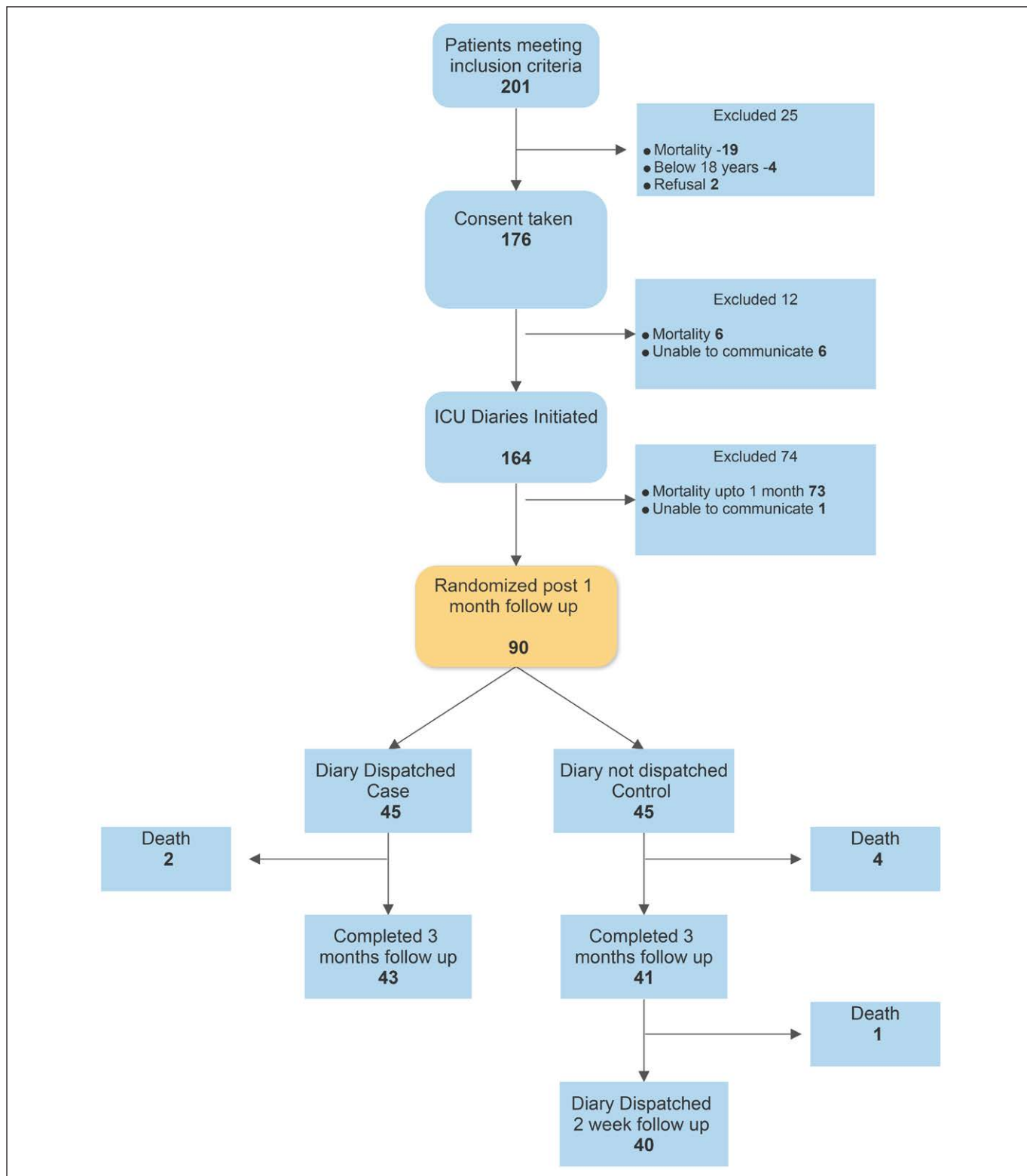


Figure 1. Flow diagram of the progress through the study phases.

beyond primary school, and 50 had risk factors for worse MH outcomes (young age, greater severity of illness, prior stressful life experiences, deep planes of sedation, and poor QOL at ICU discharge) as determined by our previous study (10). The indications for ICU admission were respiratory ($n = 29$), toxicological, for example, organophosphorus poisoning or snake bites ($n = 19$), acute abdomen, such as acute pancreatitis, perforation peritonitis ($n = 11$), neurologic ($n = 7$), septic shock ($n = 5$), and trauma ($n = 5$). All patients were mechanically ventilated for at least 24 hours, a mean of 3.7 ± 3.2 days. The mean APACHE-II score at admission was 13.7 ± 4.9 , and the length of stay in ICU was 8.2 ± 7.1 days. Further details of patient and ICU characteristics appear in **Table 1**.

Effect of ICU Diary on Mental Health and QOL

Unpaired t tests between groups were similar for QOL, PTSS, and Anxiety-Depression at discharge and 1

month (before randomization). However, the avoidance scores (a PTSS subset) of ID1 were higher than that in ID3 at both time points (**Supplement Table B**, <http://links.lww.com/CCX/B37>).

Outcomes between the groups are illustrated in **Figure 2** (**Supplement Table C**, <http://links.lww.com/CCX/B38>, shows the corresponding numbers). An independent sample t test to compare the change of scores between ICU discharge and 1 month showed no difference between the two groups. Scores between 1 and 3 months showed a significant drop in PTSS and anxiety-depression scores across all domains in the ID1. The difference in change in QOL over time was not significant between the groups (**Table 2**). ID3 scores showed a significant within-group decrease (improvement) in the assessment at 15 days after receiving their diaries across all outcome parameters, including QOL (**Supplement Table D**, <http://links.lww.com/CCX/B39>).

TABLE 1.
Comparison of Baseline Characteristics and Outcomes Between the Two Groups

Variable	All Patients ($n = 84$)	ID1 ($n = 43$)	ID3 ($n = 41$)	p
Demographic characteristics				
Age, mean (sd), yr	46.7 (17.2)	46.9 (17.0)	46.6 (17.6)	0.93
Educated ^a	49 (58.3)	24 (58.5)	25 (58.1)	0.97
Married	76 (90.5)	37 (90.2)	39 (90.7)	0.94
Have young children	20 (23.8)	9 (22.0)	11 (25.6)	0.7
Employed	39 (46.4)	20 (48.8)	19 (44.2)	0.67
Post-traumatic stress disorder risk ^b	50 (59.5)	25 (61)	25 (58)	0.66
Use of steroids	31 (36.9)	13 (31.7)	18 (41.9)	0.34
Illness severity (all values are mean, sd)				
Carlson's Comorbidity Index	1.3 (1.4)	1.2 (1.3)	1.3 (1.5)	0.79
Acute Physiology and Chronic Health Evaluation II	13.7 (4.9)	13.7 (4.4)	13.6 (5.5)	0.94
Sequential Organ Failure Assessment	5.9 (3.0)	5.8 (2.9)	5.9 (3.0)	0.88
Treatment and outcome parameters				
Benzodiazepine (mg/d)	2.1 (1.5)	2.3 (1.4)	1.9 (1.5)	0.33
Visual Analog Scale	3.5 (0.8)	3.5 (0.9)	3.5 (0.9)	0.99
Richmond Agitation Sedation Score	-1.1 (1.2)	-0.9 (1.11)	-1.16 (1.3)	0.43
Mechanical ventilation, d	3.7 (3.2)	3.5 (2.1)	3.8 (3.9)	0.62
ICU length of stay, d	8.2 (7.1)	7.8 (4.3)	8.4 (9.1)	0.63

^aEducated indicates primary schooling or beyond.

^bPost-traumatic stress disorder risk is defined as per the response to the Brief Trauma Questionnaire; midazolam and lorazepam are used; dose in mg/d is calculated as midazolam equivalent where 1-mg IV lorazepam is equivalent to 2-mg midazolam (IV).

All values are expressed as n (%) unless specified; ID1 group for which ICU diaries were dispatched at 1 mo. ID3 group for which diaries were dispatched after 3-mo assessment.

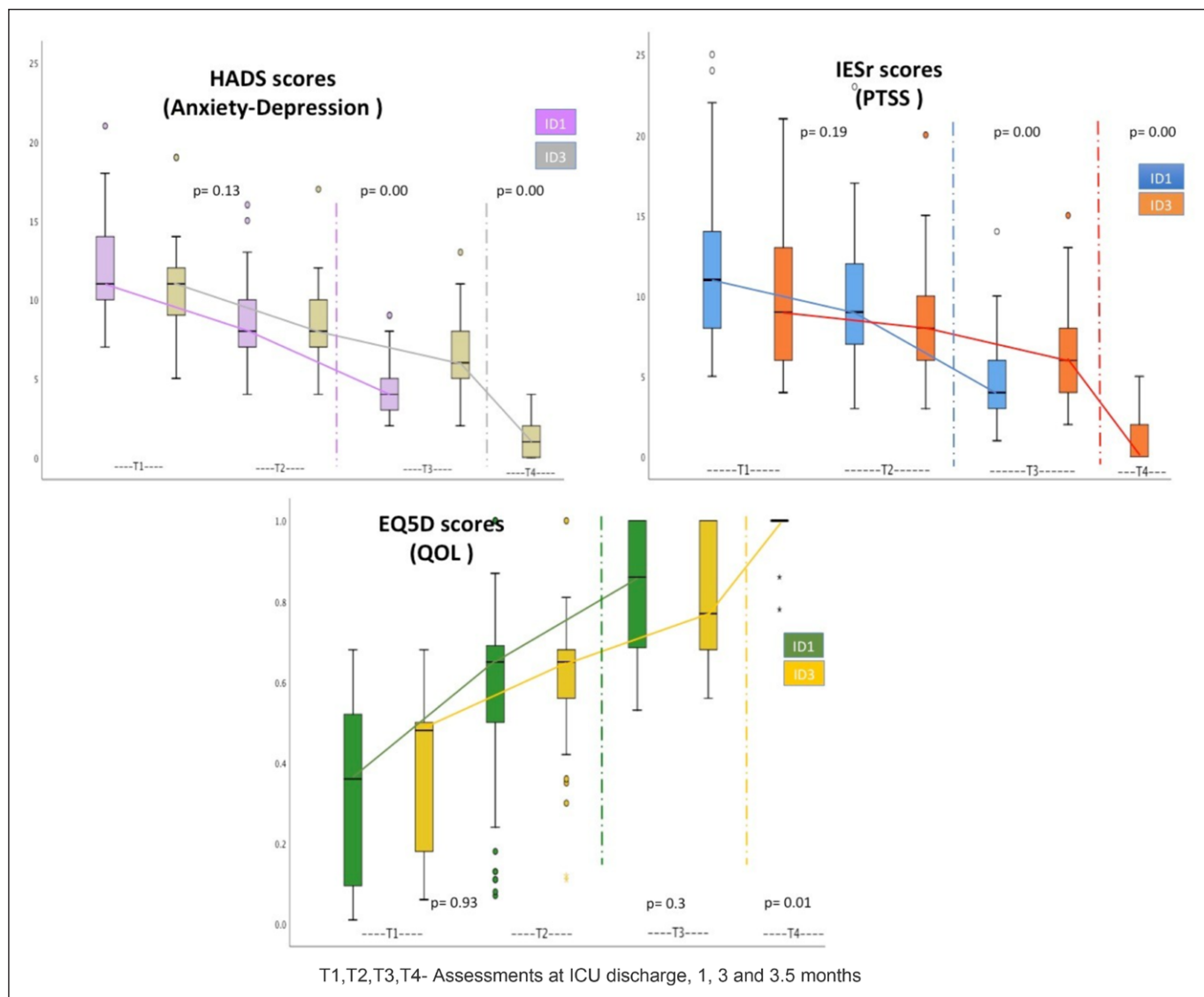


Figure 2. Box plots comparing the outcome scores between the two groups (ID1 and ID3) over time. T1, T2, T3, and T4 are time points at discharge, 1-mo, 3-mo, and 3.5-mo follow-up. *Last panel in each graph* shows the improvement in outcomes in ID3 between 3 and 3.5 mo. ■■■ represents the dispatch of ICU diary (after 1- and 3-mo assessments for groups ID1 and ID3, respectively). EQ5D = European Quality of Life 5 Dimensions, HADS = Hospital Anxiety-Depression Scale, IESr = Impact of Events Revised, QOL = quality of life.

Effect of ICU Diary on Memories

The ICU diary’s effect on memories was studied by comparing memories before and after getting the diary. An increase in delusional memories in the ID1 group was noted (statistically nonsignificant) at 3 months’ assessment, but not for other memory types. Memories of feeling ($p = 0.04$) and delusion ($p < 0.01$) showed a significant increase from prediary levels in ID3 patients when assessed 15 days after getting the diary (Supplement Table D, <http://links.lww.com/CCX/B39>).

DISCUSSION

We believe ours to be the first RCT exploring ICU diaries’ effect on patient outcomes from a low, middle-income country. We created ICU diaries for all enrolled patients: one group (ICU diary 1—ID1) received them at 1 month of ICU discharge, whereas the other group (ICU diary 3—ID3) received it after 3 months, enabling an intergroup comparison for effect of ICU diaries at three months. Next, we dispatched the diaries for the ID3 group, assessing for outcomes after 2 weeks, such that this group acted as its own control. We found that

TABLE 2.**Comparison of Change in Outcome Scores in the Two Groups: Assessment at 1 Versus 3 Months**

Outcome Variable	Group ID1 (n = 43), Mean Difference (SD)	Group ID3 (n = 41), Mean Difference (SD)	Mean Difference, Mean (SE)	95% CI, Lower–Upper	p
Anxiety-depression	4.16 (1.99)	2.15 (1.81)	2.01 (0.41)	1.2–2.8	< 0.001
Anxiety	1.91 (1.34)	1.05 (1.26)	0.86 (0.28)	0.29–1.4	0.003
Depression	2.26 (1.25)	1.1 (1.35)	1.16 (0.28)	0.6–1.7	< 0.001
Post-traumatic stress symptoms	4.81 (2.32)	2.27 (2.36)	2.54 (0.51)	1.53–3.56	< 0.001
Intrusion	2.02 (1.37)	0.98 (1.27)	1.05 (0.29)	0.47–1.6	0.001
Avoidance	0.79 (0.88)	0.27 (0.5)	0.52 (0.1)	0.21–0.83	0.001
Hyperarousal	2.02 (1.45)	0.98 (1.19)	1.04 (0.3)	0.47–1.6	0.001
Quality of life	0.27 (0.21)	0.22 (0.18)	0.04 (0.04)	0.04–0.13	0.3

All values indicate the difference in scores as mean difference (SD) between D30 and D90 assessments for each group; ID1 received ICU diary on D30 while ID3 did not receive the ICU diary. Anxiety-depression was assessed using the Hospital Anxiety-Depression Scale, post-traumatic stress symptoms, quality of life (Euro Quality of Life 3 dimensions), and CI.

patients who received the ICU diary had better MH outcomes across all domains than those who did not. Once the other group received the diaries, their scores improved. ICU memories and QOL showed a significant change (increase) in the ID3 group after receiving their diaries, but not in the ID1 group.

Evidence from previous studies on ICU diaries is divided. Like us, Barreto et al (22) found ICU diaries to improve depression (and QOL) among patients from 12 pooled studies. Parker and Bienvenu (23) found improved PTSS in a meta-analysis from European ICUs. Bäckman et al (24) found significantly better QOL in the diary group. An improvement in memories and anxiety-depression scores in the ICU diary group was seen by Fukuda et al (25). However, some studies did not find benefits (26) and even described harm from ICU diaries (27, 28). This discrepancy may be narrowed down to differences between study designs such as patient selection, randomization, diary design, and population. We discuss these in the context of our results.

Patient Selection

An intervention (ICU diary) will intuitively have maximum effect in a carefully selected population, at higher risk of poor MH outcome. As the evidence for rates, risk factors, and treatment of post-ICU MH outcomes has been controversial on many fronts, the results of studies looking at the effect of ICU diaries have been inconsistent (7, 9, 29–32). A recent RCT admits that improper

patient selection might have resulted in negative results (33). Since little was known in our population, we first identified risk factors and used this information to maximize the recruitment of patients fulfilling these criteria (10, 11). The psychologist counseled all patients, checking for known risk factors—encouraging participation, resulting in meager refusal rates.

Diary Design

The design and family engagement determine diary utilization. Often a large percentage of entries are not legible, and comprehension is not assessed, affecting utilization (26). The design of our diary was iteratively adapted to user feedback. Each HCW entry was transcribed into the local language Odia (for both groups) and read out to family members in the first few days to improve acceptance of the study. For instance, although photographs of patients in the ICU were not allowed in the ICU Diary study (34), our family members approved, and patients found photographs showing the improvement a source of encouragement. Two patients reported that they would not have liked to see their ICU photos prior to discharge from the hospital as it would have scared them, but welcomed the photographs later.

Diary Distribution

In most studies, an ICU diary has been created only for the intervention group. This might introduce a bias

among healthcare workers, patients, and families of the control group. Indeed, at times, influenced by the ongoing study, control group members have initiated diaries themselves. The timing of diary dispatch is important and has varied between studies. PTSS typically begins after 1 month of the trauma: the reason why we dispatched the diaries to the ID1 group after the common 1-month baseline assessment of both groups. Reliving ICU stay by seeing the diary too early after discharge may reduce the effect and worsen outcomes, as observed by a recent negative trial where the ICU diary group had significantly greater PTSS (35). Both groups in our study were treated the same. Family members of both groups witnessed their diaries being sealed in an envelope at ICU discharge. They were informed that it would be posted after the 1-month interview and reach them anytime within 3 months as a “gift and remembrance” from the ICU team.

Patient Dropout

Dropout of patients from a trial affects its results. Previous studies show dropout rates of up to 42% (35). Patients at a greater risk of worse outcomes are more liable to be lost to follow-up (33). However, the rapport with the patient family and robust home visits ensured that of eligible patients, 88% consented, and 100% of alive patients completed the 3-month follow-up.

Our study's control arm (ID3) also had diaries created and sent to them, allowing for a within-group comparison of outcomes 15 days after receiving the diary. No other RCT has done this prior to our study. The benefit in the control arm patients reiterates the benefit of the ICU diary and demonstrates an improved QOL, highlighting the effect of time on outcome evaluation. In the ID1 group, only delusion memories were increased (not reaching statistical significance) at 3 months of assessment, whereas in ID3, having seen the diaries within the last 15 days, delusion and feeling memories were significantly increased. We hypothesize that it was the clarification/refreshing of the delusional memories, which might have had maximum impact and, therefore, retained the longest.

There are some limitations to our study. It is a single-center trial, and although QOL scores were better in the intervention group at 3 months, the study was underpowered to uncover a significant difference in QOL in the RCT. Although we confirmed in two follow-up calls that all the patients had used the diary after receipt, we did not assess the relation of outcomes to the patients'

“dose” of diary usage. The effect of short-term improvement seen in our study, on long-term outcomes (beyond 3 mo), will need to be addressed in future studies.

CONCLUSIONS

An ICU diary, acceptable in design and format to family members and administered between 1 and 3 months of ICU discharge, may improve MH outcomes and ICU-related memory in ICU patients in LMIC settings. ICU diaries may be routinely used. More extensive or longer term studies are needed to demonstrate the influence on QOL and other clinical outcome parameters.

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