**Official Title:**

# Feasibility, Acceptability and Efficacy of a Family-authored Digital ICU Diary Intervention for Bereaved Family Members in Hong Kong Intensive Care Units: A Pilot Randomised Controlled Trial With Qualitative Process Evaluation

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# Study Protocol

## Family-authored Digital ICU Diary Intervention to Support Bereaved Family Members in Intensive Care Unit: A Pilot Mixed Methods Study

**Investigators**

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## Study Background

Significance of end-of-life care in intensive care units

The experience of family members facing death in intensive care units (ICU) differs notably from other healthcare settings, characterised by precipitous transitions from recovery expectations to death inevitability. Despite advanced interventions improving survival, ICU mortality rates remain the highest among inpatient units.

Unique position and vulnerability of family members in the intensive care unit

ICU family members occupy dual roles as vulnerable care recipients experiencing psychological distress and as decision-makers who can best reflect patients' wishes. Studies indicate prevalence rates of up to 73% for anxiety, 35% for depression, 56% for Post-Traumatic Stress Disorder (PTSD), and 52% for complicated grief among ICU family members. Family members participate in end-of-life decision-making because: i) they can best reflect patients' wishes; ii) they represent patients' best interests legally; iii) collective decision-making aligns with Asian cultural norms; iv) they are considered healthcare service customers. This research uses 'family members' rather than 'next-of-kin' or 'surrogate', acknowledging Hong Kong's Confucian familism context.

Evidence of a digital Intensive care unit diary

ICU diaries originated in Denmark in 1984 to 'fill in memory gaps' for ICU patients. Meta-analyses demonstrate that nurse-authored ICU diaries reduce PTSD (OR 0.63, 95% CI 0.45, 0.87) and depression (OR 0.63, 95% CI 0.45, 0.87) in patients.

However, the impact on family members' psychological outcomes remains inconclusive. Reviews show mixed results for PTSD, anxiety, and depression. Three gaps exist: First, systematic reviews haven't distinguished between clinician-authored and family-authored diaries, despite potential psychological benefits for family members who author diaries themselves. Second, no Randomised Controlled Trials (RCT)s have included bereaved family members, though qualitative evidence suggests ICU diaries help family members understand their loved one's illness and cope with loss. Third, while digital ICU diaries have been examined, recent RCTs predominantly use hand-written diaries. Family-authored digital ICU diaries could overcome barriers by enabling remote contributions without increasing staff workload.

Contextual Appropriateness in Hong Kong

No study has evaluated bereaved ICU family members in Hong Kong despite their vulnerability. Pilot interviews identified lack of support for family members during treatment withdrawal decisions and after death, despite approximately half of ICU deaths following treatment withdrawal. This study aims to pilot the feasibility and acceptability of a family-authored digital ICU diary intervention for bereaved ICU family members across Hong Kong ICUs.

## Study Objective

The primary aim of this research is to evaluate the feasibility, acceptability and appropriateness of a family-authored digital ICU diary intervention for bereaved family members in Hong Kong ICUs.

Secondary aims include:

- Understanding family members' experiences of writing the digital diary during and after the patient's dying and death in the ICU
- Evaluating the efficacy of the digital ICU diary intervention on family members' PTSD, anxiety and depression

Hypothesis

We hypothesise that the digital ICU diary is feasible, acceptable and potentially efficacious for bereaved family members' PTSD, anxiety and depression at 1 month (T1) and 3 months (T2) following the patient's death compared to baseline measurements taken at the transition time of medical consideration from curative to life-sustaining treatment of a patient in ICU. Compared to the control group, the intervention group will have lower scores on the Impact of Event Scale-Revised (IES-R), Posttraumatic Stress Syndrome-14 (PTSS-14), and Hospital Anxiety and Depression Scale (HADS) at T1 and T2.

## Study Design

This two-arm, assessor-blind pilot RCT includes a quantitative component with qualitative process evaluation. Following consultations with bereaved ICU families and clinicians, the intervention was modified to include bilingual diary options, culturally sensitive prompts, and WhatsApp delivery. Eligible participants undergo 1:1 block randomisation to either the digital ICU diary intervention or control groups, with assessments at baseline (T0), 1-month (T1), and 3-month post-patient death (T2).

Intervention Group

Participants receive standard care, including hospital information about ICU procedures, visiting hours, regular medical updates during critical illness, and post-death support for funeral procedures, death certification, and transport arrangements.

The intervention begins when life-sustaining treatment is considered, continues through ICU death, and extends one month into bereavement. When clinicians initiate end-of-life discussions, eligible family members are invited to participate. Following consent and randomisation, intervention participants receive comprehensive digital ICU diary instructions via printed materials and WhatsApp messages from Research Assistant(RA)1.

Instructional materials, based on established RCT protocols for family-authored ICU diaries, detail the diary's purpose, content guidelines, boundaries, writing approaches, and prompt questions. Privacy safeguards discourage documenting excessively personal content. The WhatsApp format accommodates convenient writing within guidelines, with audio recordings accepted as alternatives.

Participants are encouraged to document experiences at least twice weekly during ICU visits using preferred expression forms. RA1 sends bi-weekly

WhatsApp reminders to support consistent participation. Participants receive HKD 200 incentives at each assessment point (T0, T1, T2) to encourage engagement.

Control Group

The control group will receive the standard care without the digital ICU diary intervention. Participants in this group will be invited to complete questionnaires at T0, T1 and T2, receiving incentives of HKD 200 for each participation.

Assessor-Blind Methodology

To ensure rigour despite limited ICU visiting hours and potential contamination, the outcome assessor (RA1) and statistician remain blinded throughout. Blinding measures include: anonymising groups as 'A' and 'B' during analysis; instructing participants against revealing allocation; excluding the intervention-delivering RA2 from assessments; and conducting separate team meetings for intervention and evaluation activities.

Randomisation Process

One family member per patient undergoes block randomisation (block size: 4) using computer-generated sequences. An independent researcher prepares sealed, sequentially numbered, non-transparent envelopes opened by RA2 with the Co-A present at each site, separate from baseline assessment. RA1 remains blinded to assignments while conducting outcome assessments.

**Subjects**

Family members of ICU patients who are under medical consideration for life-sustaining treatment. One family member of the patient who 1) is the closest to the patient (spouse, grown child or parents) and 2) visits the ICU most often, will be chosen.

Inclusion criteria:

- Aged 18 years or above
- One family member of each patient whose treatment was considered life-sustaining in the ICU
- Family member of a patient who has been admitted to ICU for a minimum of 48 hours
- Family members of a patient who dies in ICU without transfer to other inpatient units
- Able to read, write and communicate effectively in Chinese or English

Exclusion criteria:

- Currently diagnosed with a psychiatric disease and currently taking a psychotropic medication
- Currently participating in any type of psychological intervention
- Have a cognitive impairment

Sampling method:

Participant recruitment will be conducted in the ICUs of three tertiary public hospitals: Ruttonjee Hospital, Tuen Mun Hospital and Queen Elizabeth Hospital. Co-Applicants—Dr CK Tong (intensivist), Mr SC Mok (ICU Advanced Practice Nurse) and Mr CSS Chan (ICU Associate Nurse Consultant)—will identify potential family member participants and invite them to participate in the research when a patient's treatment is considered life-sustaining in the ICU and end-of-life conversations are being initiated. Upon receiving consent from family members, Co-Applicants will forward their contact details to the RA assigned to this project. The RA will then contact potential participants to provide information about the research, reassess their eligibility for participation and extend a formal invitation to participate. Those who agree to take part will be asked to provide written informed consent. Participants will receive cash of HKD 200 upon completion of each assessment (T0, T1 and T2) and interview. These incentives are intended to enhance participation rates and follow-up compliance.

Demographics of the sample:
Background Questionnaire will be administered at T0 to collect participants' demographic characteristics (age, gender, education level, relationship to patient, religious affiliation), previous experience with bereavement and pre-existing psychological conditions. Information about the patient's ICU stay duration, diagnosis and treatment will also be included.

Participation incentives:
Participants will receive incentives of HKD 200 at each of the three assessments at T0, T1 and T2.

Anticipated benefits to study participants:
Whilst there may be no immediate benefit to participants, this study aims to evaluate bereaved ICU family members in Hong Kong despite their vulnerability and potential psychological distress. The findings from this study will contribute to the evidence base for developing a family-authored digital ICU diary intervention across Hong Kong ICUs to support the bereaved family members.

## Sample Size

Since there is no preliminary research of ICU bereaved family member recruitment for RCT study, the sample size was determined to be 40 based on power analysis for pilot RCT. 20 participants are required for each intervention using a medium effect size with 80% power and a 5% significance level. Participants will be allocated to intervention and control groups in a 1:1 ratio. All 20 participants in the intervention group will be invited to take part in the qualitative process evaluation.

## Primary and Secondary Outcome Measure(s)

Primary outcome:

- Likert-scale items on feasibility, acceptability and appropriateness of the diary
- Diary completeness
- Frequency and number of diary entries

- Qualitative interview data on diary-use experiences

Secondary outcomes:
Efficacy-related outcomes:
- Impact of Event Scale-Revised (IES-R)
- Posttraumatic Stress Syndrome-14 (PTSS-14)
- Hospital Anxiety and Depression Scale (HADS)
- Background demographics

## Methods of Data Analysis

Statistical Analysis
Demographic characteristics of participants and recruitment rate, retention rate and intervention adherence in feasibility-related outcomes will be summarised using descriptive statistics. For continuous variables, means and standard deviations will be reported for normally distributed data, whilst medians and interquartile ranges will be presented for non-normally distributed data. Categorical variables will be expressed as frequencies and percentages. Feasibility, acceptability and appropriateness assessed by FIM, AIM, and IAM. The analysis of efficacy-related outcomes will follow an intention-to-treat approach, wherein participants who withdraw will be treated as having no change from baseline. Between-group differences in IES-R, PTSS-14, and HADS scores across all time points (baseline, T1, and T2) will be compared using repeated measures ANOVA for normally distributed data or appropriate non-parametric alternatives for non-normally distributed data.

Standardised mean differences between intervention and control groups will be calculated with 95% confidence intervals, presented both unadjusted and adjusted for baseline characteristics. Linear mixed effects models will be employed for all primary efficacy outcomes (IES-R, PTSS-14, and HADS scores) to investigate between-group and within-group changes whilst adjusting for covariates (age, gender, education level, relationship to patient, religious affiliation, previous bereavement experiences). These models will accommodate missing data. Multiple regression analyses will explore the influence of diary usage patterns (frequency, duration, content characteristics) on changes in psychological outcomes.
All statistical tests will be two-sided with a significance level $p<0.05$. For the process of study conduct and reporting, we will strictly adhere to the CONSORT extension for pilot and feasibility trials.

Qualitative Analysis
Qualitative process evaluation will be conducted at T2. All participants in the intervention group will be invited for an individual face-to-face semi-structured interview to capture participants' diverse intervention experiences. Interview recordings will be audio-recorded, transcribed verbatim and analysed using NVivo. Thematic analysis following Braun and Clarke's approach will be used for analysing qualitative data. Triangulations and member checks will be employed to ensure the trustworthiness of qualitative research.

## Direct Access to Source Data/Documents

The investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.

**Quality Control and Quality Assurance**

The study will be conducted according to the Declaration of Helsinki. The protocol will be submitted to the Hospital Authority Central Institutional Review Board (Central IRB) for approval.

**Data Handling and Record Keeping**

- Personal data will be stored during and after the study.
- All personal and study data will be handled and stored in strict compliance with institutional ethical standards, the Hong Kong Personal Data (Privacy) Ordinance (Cap. 486), and HMRF data management policies. During the study, personal data such as participants' names, contact information, and consent forms will be stored separately from research data to ensure confidentiality. All identifiable information will be kept in encrypted, password-protected files on the University of Hong Kong's secure, access-controlled server. Any hard copy materials, including consent forms, will be locked in secure cabinets accessible only to authorised project personnel. All interview recordings will be coded with unique identifiers, and transcripts will use pseudonyms to remove identifying details. Electronic data transfer between research sites and the university will occur through encrypted channels to maintain data security. After the study, all personal identifiers will be permanently removed or anonymised from the datasets before final analysis. Audio recordings will be destroyed once transcription checks are completed. The de-identified datasets will be stored on the HKU secure research archive for five years to allow for verification or audit, after which they will be permanently deleted. Publications and presentations will report only aggregated findings, ensuring that no individual participant can be identified. This approach guarantees that all personal and study data are confidentially managed, securely stored, and ethically disposed of in accordance with institutional and legislative requirements.
- Access to personal and study data will be strictly limited to authorised research personnel. During the study, only the Principal Investigator (PI), Co-Investigators, and designated Research Assistants (RAs) responsible for data collection, management, and analysis will have access to identifiable personal data such as contact details and consent forms. The RAs will handle participant recruitment, data entry, and follow-up, while maintaining confidentiality under close supervision of the PI. All individuals with access will have completed institutional research ethics and data protection training. In addition, the lead and site principal investigators will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.
- Lead Principal Investigator, Dr Hye Ri Choi, will be responsible for the safekeeping of the personal and study data during and after the study.
- The personal and study data be kept after the study for 5 years.
- After the storage period, all study data will be destroyed appropriately by overriding each file. Hard copies will be discarded as confidential waste,

while the soft copies will be deleted and unrecoverable after the storage period.

All data will be handled confidentially and stored securely. Participant information will be de-identified and assigned unique identification codes. Only the research team will have access to the data. All research data will be retained for a minimum period as required by institutional policy and regulatory requirements.

**Financing and Insurance**

This research is supported by the Health and Medical Research Fund (HMRF).

**Publication Policy**

The digital ICU Intervention for bereaved family members who have experienced the death of a loved one holds particular significance, both due to their psychological vulnerability and the paucity of bereavement support services in Hong Kong. The research findings shall be disseminated to clinicians currently providing care and treatment in ICUs. These practitioners will be encouraged to share the findings with colleagues to heighten awareness of family members' vulnerabilities and recognise the value of the digital ICU diary intervention. Furthermore, by submitting the report to the Hospital Authority, this study will provide empirical evidence regarding the digital ICU diary intervention, addressing the current gap in care services for bereaved family members in ICU settings. Lastly, the findings shall be disseminated to academic researchers and the wider public through publication in international research conferences, international peer-reviewed journals.

**Ethical Concern**

The study participants are not anticipated to experience any physical or psychological harm. Potential participants will be informed about the research and invited to participate in advance, in case they might feel uncomfortable with the research content. Participation in the study is voluntary. Only those who agree to participate will continue completing the digital diary, representing implied consent. Additionally, participants will be given the opportunity to withdraw at any point prior to or during the interview.

To protect anonymity and confidentiality, each participant will be assigned a unique study code, and no directly identifying information (such as name, HKID number, or contact details) will be included in the research dataset. Digital diary entries, interview recordings, and transcripts will be stored on password-protected, access-restricted servers at the University of Hong Kong. Only the principal investigator and authorised research team members will have access to identifiable data. Audio recordings will be transcribed and anonymised, with all personal identifiers removed before analysis. In any reports, publications, or presentations, data will be presented in aggregate or using pseudonyms so that individual participants cannot be identified. Data will be retained and destroyed in accordance with institutional and regulatory requirements.

In order to ensure voluntary participation, an information sheet and consent form will be provided beforehand. After giving potential participants sufficient time (at least a day) for consideration, only those who agree to participate will be invited to the study.

**Potential hazards to participants**

The study participation will be a significant difference from usual management since it is not mandatory. However, this pilot mixed-methods study poses no physical harm. Participants are bereaved ICU family members invited to author a WhatsApp-based ICU diary and complete questionnaires at baseline, 1 and 3 months; intervention participants also have a 3-month interview. Participation allows expression and organisation of experiences, not alteration of care. Psychological distress is expected to be minimal but possible; we will ask in advance about vulnerability and exclude those with psychiatric disease on psychotropic medication, current psychological intervention, or cognitive impairment. Any participant expressing distress will be withdrawn immediately and referred to mental health services.

## Literature Reference


1. Choi HR, Ho MH, Lin CC. Treatment futility: Continuation or withdrawal of life-sustaining treatment in intensive care units. Intensive & Critical Care Nursing. 2025.
2. Vincent J-L, Marshall JC, Ñamendys-Silva SA, François B, Martin-Loeches I, Lipman J, et al. Assessment of the worldwide burden of critical illness: the intensive care over nations (ICON) audit. The Lancet Respiratory Medicine. 2014;2(5):380-6.
3. Choi HR, Ho Mh, Lin CC. Navigating tensions when life-sustaining treatment is withdrawn: A thematic synthesis of nurses' and physicians' experiences. Journal of Clinical Nursing. 2024;33(6):2337-56.
4. Zante B, Camenisch SA, Schefold JC. Interventions in post-intensive care syndrome-family: a systematic literature review. Critical care medicine. 2020;48(9):e835-e40.
5. Galazzi A, Adamini I, Bazzano G, Cancelli L, Fridh I, Laquintana D, et al. Intensive care unit diaries to help bereaved family members in their grieving process: a systematic review. Intensive and Critical Care Nursing. 2022;68:103121.
6. Choi HR, Rodgers S, Tocher J, Kang SW. Nurse's, physician's and family member's experiences of withholding or withdrawing life-sustaining treatment process in an intensive care unit. Journal of Clinical Nursing. 2023;32(15-16):4827-42.
7. McIlroy PA, King RS, Garrouste-Orgeas M, Tabah A, Ramanan M. The effect of ICU diaries on psychological outcomes and quality of life of survivors of critical illness and their relatives: a systematic review and meta-analysis. Critical Care Medicine. 2019;47(2):273-9.
8. Barreto BB, Luz M, Rios MNdO, Lopes AA, Gusmao-Flores D. The impact of intensive care unit diaries on patients' and relatives' outcomes: a systematic review and meta-analysis. Critical Care. 2019;23:1-10.
9. Huang W, Gao Y, Zhou L, Xiao X, Xu H, Lu L, et al. Effects of ICU diaries on psychological disorders and sleep quality in critically ill patients and their family members: A systematic review and meta-analysis. Sleep Medicine. 2024.
10. Nielsen AH, Angel S, Egerod I, Hansen TB. The effect of diaries written by relatives for intensive care patients on posttraumatic stress (DRIP study): protocol for a randomized controlled trial and mixed methods study. BMC Nursing. 2018;17:1-10.
11. Mickelson RS, Piras SE, Brown L, Carlile C, Drumright KS, Boehm L. The use and usefulness of ICU diaries to support family members of critically ill patients. Journal of Critical Care. 2021;61:168-76.
12. van Mol MM, Tummers N, Leerentveld C, Tieben R, Buise M. The usability of a digital diary from the perspectives of intensive care patients' relatives: A pilot study. Nursing in Critical Care. 2024;29(6):1280-9.
13. Cornelius T, Mendieta M, Cumella RM, Lopez Veneros D, Tincher IM, Agarwal S, et al. Family-authored ICU diaries to reduce fear in patients experiencing a cardiac arrest (FAID fear): a pilot randomized controlled trial. PloS One. 2023;18(7):e0288436.

14. Lai VKW, Ho KM, Wong WT, Leung P, Gomersall CD, Underwood MJ, et al. Effect of preoperative education and ICU tour on patient and family satisfaction and anxiety in the intensive care unit after elective cardiac surgery: a randomised controlled trial. BMJ Quality & Safety. 2021;30(3):228-35.
15. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. Implementation Science. 2017;12:1-12.
16. Mok LC, Lee IFK. Anxiety, depression and pain intensity in patients with low back pain who are admitted to acute care hospitals. Journal of Clinical Nursing. 2008;17(11):1471-80.
17. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. Statistical Methods in Medical Research. 2016;25(3):1057-73.

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# Project title

## Family-authored Digital ICU Diary Intervention to Support Bereaved Family Members in Intensive Care Unit: A Pilot Mixed Methods Study

## Informed Consent Form

I hereby consent to participate in the research study.

I have read the **PARTICIPANT INFORMATION SHEET.** The study has been explained to me by investigator(s). I understood all the benefits and the risks associated with this study. I have had opportunities to ask questions and all my questions have been satisfactorily answered. I have received enough information about the study.

If participation in this study has caused me any physical injury or uncomfortable emotion, the investigator will treat me or refer me for treatment. I am not giving up any of my legal rights by signing this form.

By signing this consent form, I certify that all information provided is true and correct. I understand that my participation is voluntary. I am free to withdraw from the study at any time, without giving any reason for withdrawing, and the withdrawal will not affect my present and future medical care or my legal rights.

If I request to withdraw from this study, I ☐ agree / ☐ disagree my research data provided before my withdrawal will be continuously used by the investigator.

I understand that the interview will be audio-recorded and that all recordings will be anonymised. I also understand that I may ask for the recording to be stopped at any time, and that I may refuse to answer any questions that make me feel uncomfortable, without giving a reason and without affecting my participation in the study.

I understand that my identity will be kept confidential. I agree to authorise the Research Ethics Committee (REC) and the regulatory authority(ies) direct access to my research data for verification of clinical trial data, without violating my confidentiality, to the extent permitted by the applicable laws and regulations.

| Participant's Name (in BLOCK Letter) | Participant's Signature | Date |
|---|---|---|
| Investigator/Research Assistant's Name (in BLOCK Letter) | Investigator/Research Assistant's Signature | Date |

I will be given a participant information sheet and a signed copy of this consent form.