



City Research Online

City, University of London Institutional Repository

Citation: Mitchell, M., Kean, S., Rattray, J., Hull, A., Davis, C., Murfield, J. & Aitken, L. M. (2017). A family intervention to reduce delirium in hospitalized ICU patients: a feasibility randomized controlled trial. *Intensive and Critical Care Nursing*, 40, pp. 77-84. doi: 10.1016/j.iccn.2017.01.001

This is the accepted version of the paper.

This version of the publication may differ from the final published version.

Permanent repository link: <https://city-test.eprints-hosting.org/id/eprint/16425/>

Link to published version: <https://doi.org/10.1016/j.iccn.2017.01.001>

Copyright: City Research Online aims to make research outputs of City, University of London available to a wider audience. Copyright and Moral Rights remain with the author(s) and/or copyright holders. URLs from City Research Online may be freely distributed and linked to.

Reuse: Copies of full items can be used for personal research or study, educational, or not-for-profit purposes without prior permission or charge. Provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

City Research Online:

<http://openaccess.city.ac.uk/>

publications@city.ac.uk

**A family intervention to reduce delirium in hospitalised ICU patients: a feasibility
randomised controlled trial**

Accepted for publication 2017: Intensive and Critical Care Nursing

1. **Associate Professor Marion L Mitchell** RN, PhD^{a,b,c,d,*} marion.mitchell@griffith.edu.au
2. **Dr Susanne Kean** RN, PhD^e Susanne.Kean@ed.ac.uk
3. **Dr Janice E Ratray** RN, PhD^f j.z.ratray@dundee.ac.uk
4. **Dr Alastair M Hull** MD^{g,h} ahull@nhs.net
5. **Ms Chelsea Davis** RN, BN^d Chelsea.Davis@health.qld.gov.au
6. **Ms Jenny E Murfield** BSc (Hons)^{b,c} j.murfield@griffith.edu.au
7. **Professor Leanne M Aitken** RN, PhD, FAAN, FACN, FACCCN^{a,b,c,d,i}
Leanne.Aitken.1@city.ac.uk

^aNHMRC Centre for Research Excellence in Nursing, Griffith University, Nathan Campus,
Brisbane, Queensland, Australia

^bMenzies Health Institute Queensland, Griffith University, Nathan Campus, Brisbane,
Queensland, Australia

^cSchool of Nursing and Midwifery, Griffith University, Nathan Campus, Brisbane, Queensland,
Australia

^dPrincess Alexandra Hospital Intensive Care Unit, Princess Alexandra Hospital, Brisbane,
Queensland, Australia

^eSchool of Health in Social Science, University of Edinburgh, Edinburgh, UK

^fSchool of Nursing and Health Sciences, University of Dundee, Dundee, UK

^gPerth Royal Infirmary, NHS Tayside, Dundee, UK

^hDepartment of Psychiatry, University of Dundee, Dundee, UK

ⁱSchool of Health Sciences, City University London, London, UK

Corresponding author: *Associate Professor Marion Mitchell, School of Nursing and Midwifery, Health Sciences Building (N48), 170 Kessels Road, Nathan Queensland, 4111, Australia. Tel: +61 (0)7 3176 7772 (Princess Alexandra Hospital) +61 (0)7 3735 5115 (Griffith University). Email: marion.mitchell@griffith.edu.au.

A family intervention to reduce delirium in hospitalised ICU patients: a feasibility randomised controlled trial

ABSTRACT

Background: Family members could play an important role in preventing and reducing the development of delirium in Intensive Care Units (ICU) patients. This study sought to assess the feasibility of design and recruitment, and acceptability for family members and nurses of a family delivered intervention to reduce delirium in ICU patients

Method: A single centre randomised controlled trial in an Australian medical/surgical ICU was conducted. Sixty-one family members were randomised (29 in intervention and 32 in non-intervention group). Following instructions, the intervention comprised the family members providing orientation, or memory clues (family photographs, orientation to surroundings) to their relative each day. In addition, family members conducted sensory checks (vision and hearing with glasses and hearing aids); and

therapeutic or cognitive stimulation (discussing family life, reminiscing) daily. Eleven ICU nurses were interviewed to gain insight into the feasibility and acceptability of implementing the intervention from their perspective.

Results: Recruitment rate was 28% of eligible patients (recruited n=90, attrition n=1). Following instruction by the research nurse the family member delivered the intervention which was assessed to be feasible and acceptable by family members and nurses. Protocol adherence could be improved with alternative data collection methods. Nurses considered the activities acceptable.

Conclusion: The study was able to recruit, randomise, and retain family member participants. Further strategies are required to assess intervention fidelity and improve data collection.

Keywords: critical illness; delirium; families; family-centred care; feasibility studies; health care; intensive care units; nursing; person-centred care.

IMPLICATIONS FOR CLINICAL PRACTICE

- In this setting, ICU nurses were accepting of family involvement and consideration of patients' and families' needs in the highly medicalised ICU environment.
- Delirium is well recognised as detrimental to patients' ICU and future wellbeing, and use of non-pharmacological interventions that reduce its incidence and duration are desirable.
- Adequately powered studies with strong intervention fidelity and data collection methods are required to examine the relationship between a family delivered intervention and patient delirium.

INTRODUCTION

Whilst common across all healthcare settings, delirium is particularly prevalent in the Intensive Care Unit (ICU) –ranging from 45% to 84% (Brummel et al., 2014; Roberts et al., 2005) – and can lead to a number of adverse consequences including: longer ICU and hospital stay and costs (Lat et al., 2009; Milbrandt et al., 2004); reduced quality of life (Ely et al., 2004) and functional independence (Brummel et al., 2014); and psychological morbidity and cognitive impairment (Girard et al., 2010; McKinley et al., 2016; Pandharipande et al., 2013). Numerous risk factors contribute to the development of delirium in the critically ill patient, including predisposing characteristics and comorbidities (e.g., older age, cognitive impairment – Brummel and Girard (2013)), and precipitating factors related to the illness and treatment whilst in hospital (e.g., infections, sedatives – Brummel and Girard (2013)). Addressing some of the modifiable patient risk factors, such as orientation and appropriate sensory stimulation, may assist in the prevention and reduction of delirium incidence and duration in the ICU. To date, various multicomponent interventions have been successfully developed to achieve this with hospitalised non-ICU older patients (Brummel & Girard, 2013; Holroyd-Leduc et al., 2010; Hsieh et al., 2015; Inouye et al., 2000; Inouye et al., 1999; Martinez et al., 2015). Whilst the majority of these have been delivered by nursing staff, a small number have also demonstrated the potential efficacy of family members delivering similar interventions to their relative (Martinez et al., 2012; Rosenbloom-Brunton et al., 2010).

In the context of delirium development in ICU, family members could arguably play an important role in preventing and reducing the development of the syndrome, and could also help realize formal partnerships between nursing staff and family members, which are typically not integrated in practice (Mitchell et al., 2009).

Perceived by ICU nurses as a crucial link (Bergbom & Askwall, 2000), and a proxy ‘voice’ (Mitchell et al., 2009), family members’ intimate knowledge of the patient could provide the everyday background required to orientate patients to reality, and also provide a reassuring, familiar comfort. Benefits could also extend to family members, with research showing that, when involved, families perceive greater respect, support and collaboration from nursing personnel (Al-Mutair et al., 2013; Kean & Mitchell, 2014; Mitchell et al., 2009), and feel more useful, and physically and emotionally close to their relative (Mitchell & Chaboyer, 2010).

This study sought to assess the feasibility and acceptability of a family delivered intervention to reduce delirium in ICU patients. It aimed to determine: the feasibility of recruiting participants; the retention of family members through the study; the feasibility of delivering the intervention as assessed by data collection slips; nurses’ perceived acceptability of a family intervention within ICU; an effect size to inform a cautious estimate for future sample size calculations (Arnold et al., 2009).

METHODS

Design, setting, and sample

This feasibility RCT consisted of a baseline (pre-randomisation) phase followed by randomisation to either the intervention or non-intervention group. The investigators were concerned that introduction of the intervention protocol for patients in the intervention arm of the study may lead to nurses and other members of the healthcare team using some of these strategies when caring for patients in the non-intervention arm of the study, thereby leading to contamination and influencing the study outcome, that is, delirium, in the non-intervention group. The inclusion of a pre-randomisation group enabled exploration of whether the non-intervention group had

similar outcomes to those patients enrolled during the baseline phase. If we had identified a reduced incidence of delirium in both the intervention and non-intervention group compared with the baseline, one potential explanation of this would have been contamination of the non-intervention group once the intervention had commenced.

The study was conducted within the ICU of a large, 25-bed adult tertiary referral teaching hospital in Brisbane, Australia, between January 2014 and October 2015. The sample consisted of patient participants, their family members, and ICU nurses. Patient participants were eligible for the study if they were aged ≥ 16 years, expected to remain in ICU for ≥ 4 days, able to be screened for delirium, and had a family member visit. Family members were eligible based on their relative meeting the above criteria and having a close and continuing relationship with the patient. One self-selecting family member per patient was recruited. Those unable to communicate in both written and spoken English constitute a very small proportion of the ICU cohort (1%) and were excluded as translation services were not available to the research team. The first 30 family members were allocated to the pre-randomisation phase only. The following 60 eligible family members were randomised by the Research Nurses to either the intervention or non-intervention groups (1:1) via a university based on-line randomisation service. This size sample is in line with recommendations for pilot studies (Hertzog, 2008).

Eleven ICU nurses were recruited for interview via non-random purposive convenience sampling ensuring male and female nurses with varying levels of experience working in ICU were invited to participate. ICU nurses were eligible if they had provided direct patient care to at least one ICU patient who received at least one episode of the family delivered intervention. Agency or casual staff were

excluded. It was important to assess feasibility and acceptability from the nurses' perspective as they may act as 'gate-keepers' for patients and families; interventions they support are potentially more likely to be successfully introduced.

Ethical considerations

The study was granted ethical approval and permission to conduct the study in the ICU by the relevant Human Research Ethics Committees of the Princess Alexandra Hospital (HREC/12/QPAH/540) and Griffith University (NRS/02/13/HREC). The research nurse approached family members following consultation with the direct care nurses to ensure it was appropriate to do so. All family members provided written consent for their involvement in the study, and also gave proxy written consent for their participating relative. ICU nurses also provided written consent to semi-structured interviews. Copies of the signed consent and participant information forms were given to all participants. Confidentiality was assured and no identifying data were recorded with aggregate data used for reporting purposes. All data were entered into password protected computers in a locked office available only to the research team.

Intervention

Developed by an interdisciplinary international team of experts, the intervention comprised a protocol with three elements. The template for intervention description and replication (TIDieR) checklist and guide (Hoffmann et al., 2014) has been used to describe the intervention in detail (Appendix A). In brief, the elements have been used in earlier studies (Inouye et al., 2006; Inouye et al., 2000; Inouye et al., 1999; Rosenbloom-Brunton et al., 2010) and in this study included three components with

components one (orientation) and two (therapeutic engagement) compulsory and three (sensory) if applicable:

- 1) Orientation – memory clues including: writing the name of their nurse/doctor that day, and the plan of care on a daily planner; bringing in significant family photographs and individualising their bedside area; and orientating the patient to their surroundings including where they were and why, and the day, date, and time.
- 2) Therapeutic engagement – cognitive stimulation through activities such as discussing current family life events and reminiscing.
- 3) Sensory (where applicable) – checking that the patient had their glasses on and hearing aids in place/working.

The study Research Nurses provided education to the self-designated family member and explained the intervention components. Family members were asked to deliver all relevant components of the intervention at least once each day that they visited the ICU patient, with the expectation that this would occur at least four times or more. The Research Nurse remained with the family member the first time they delivered the intervention components and on subsequent occasions, ensuring that each component of the intervention was understood. The Research Nurse made no mention of the components of the intervention to the non-intervention group who were asked to complete the data sheets on each visit.

Data Collection

Demographic information was collected about all participants in the study (Tables 1 & 2). Intervention and non-intervention group activities were recorded by family members on a specifically designed, card-sized paper data slip, located at the ICU

patient's bedside. Family members were instructed to complete a data slip each time they visited the patient and to place a tick in a box for each of the listed three components of the intervention they completed that visit with any additional comments in the free text space (intervention group). The non-intervention group was asked to write down what activities they did during their time with their relative with no prompts in an effort to reduce sensitisation to the intervention. Patient delirium in the ICU was assessed by Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) (Ely et al., 2001a; Ely et al., 2001b). A positive assessment of delirium was defined as any assessment for a patient during a 24-hour period that resulted in a positive delirium score. The CAM-ICU was completed only after an initial assessment using the Richmond Agitation-Sedation Scale (RASS) (Ely et al., 2003; Sessler et al., 2002), and not undertaken if RASS scores were -4 or -5 (deep sedation or unarousable). Those patients with a RASS score of -4 or -5 were not eligible for study inclusion. The RASS and CAM-ICU are routinely used in the hospital ICU, and either the bedside nurse or the study Research Nurse assessed the patient at least once a day. Assessment of acceptability by the ICU direct care nurses was undertaken via semi-structured, digitally recorded interviews conducted upon completion of the family intervention. These were conducted in a private area of the ICU during work hours; frequently following the shift change-over when the nurse was no longer responsible for the patient. Study notes were maintained by the Research Nurse during the study, which provided general reflections on the feasibility of the study.

Data Analysis

Following data cleaning and checking for accuracy, data were entered into IBM SPSS Statistics (Version 22). Demographic characteristics are reported as frequencies or

median data as appropriate, and similarity between groups was analysed via Kruskal-Wallis H test or Pearson's Chi-square. Feasibility of recruitment was assessed by frequency data from initial eligibility screening, length of time to enrolment (defined as ICU admission to consent), to final analysis, and was assessed for group differences by the Kruskal-Wallis H test and Mann-Whitney U tests. Feasibility of intervention delivery was assessed by frequency data exploring: participant flow through the study; missing data; length of time on the study, and completion rates in the three protocols. ICU delirium rates between groups were assessed via Pearson's Chi-square test, whilst a difference in the duration of delirium days in ICU was assessed via the Mann-Whitney U test. Means and standard deviations of the study groups for delirium days were used to determine an effect size for Cohen's *d*, which was then used for sample size calculations. All quantitative data were analyzed by a research team member independent to the data collection, with statistical significance declared at $p < 0.05$.

Thematic analysis of the study field notes (Thorne, 2013) identified patterns in relation to limitations/barriers to recruitment, and also issues pertaining to the feasibility of family members delivering the intervention. ICU nurses' interviews were transcribed verbatim, and two of the study authors independently developed themes following familiarisation, code generation and reviewing to identify themes to explore the feasibility and acceptability of family interventions in ICU. The identified themes were initially discussed between these two authors for inter-coder agreement and then by the entire research team.

RESULTS

Sample characteristics

There were 91 patient participants in the overall study cohort (30 in the pre-randomisation group; 32 in the non-intervention; and 29 in the intervention group), and 61 family members. Their characteristics (for example: gender, age, ICU LOS) were representative of the site ICU population for those patient with an ICU LOS greater than 4 days. There were no significant differences in the profile of patient participants between groups (Table 1), nor the profile of family members between groups (Table 2). Eleven ICU nurses were interviewed. Most were female Registered Nurses (RNs) (73%), with postgraduate qualifications (64%), and ≤ 5 years' experience as a nurse generally (46%), and also within ICU specifically (55%).

Recruitment

The study achieved a relatively low recruitment rate of 28%, with 91 patient participants enrolled from a total of 322 eligible patients. Patient non-consent only accounted for 13% ($n=31$) of all exclusions, with failure to capture by study personnel the principal reason ($n=169$; 73%) (Figure 1). Length of time from ICU admission to study enrolment was a median of five days (IQR 4), with no significant differences in enrolment times between control and intervention groups ($p=0.51$).

Study Research Nurse's field notes highlighted five recurring issues that hindered recruitment: 1) infrequent family visits, often due to the nature of the diverse geographical location of family members (15 comments); 2) complex family members/social situations (9 comments); 3) families' perceptions that the study would add to stress and detract attention from their sick relative (6 comments); 4) patient delirium or associated symptoms considered likely due to pre-existing clinical conditions, (5 comments); and 5) limited Research Nurse hours resulting in missed opportunities to meet with families and seek enrolment (14 comments).

Retention of family members

Retention of family members through the study was excellent. No family member withdrew from the intervention group, and only one withdrew from the control group – after two days because of the family’s concerns with regularly performed CAM-ICUs on their relative (despite this being the hospital ICU’s policy).

Feasibility and acceptability of the intervention

A quarter (24%, $n=7$) of family members in the intervention group did not complete any data slips; 13% ($n=4$) did not record any in the non-intervention group. Research Nurse’s field notes suggested that the requirement to complete data slips was, for some families, “*too much*”. Family members commented that the components of the intervention were not difficult or onerous to implement.

Whilst participants were enrolled in the intervention group (from consent to ICU discharge) for a median of five days (IQR 6) – which is comparable to the non-intervention group (median 5; IQR 4) – recorded data slips for the three protocols were low. Specifically, the family members recorded data slips for the therapeutic protocol for a median of 2 days (IQR 4), the orientation protocol for 1 day (IQR 3), and the sensory protocol for a median of 0 days (IQR 2) (Figure 2). Consistent daily completion of data slips was not achieved, with activity data available for just 35% of therapeutic activities, 30% of orientation, and 20% of sensory checks.

ICU Nurses were generally favourable about the family members’ involvement in the three protocols, recognising the importance of a tailored approach for the ICU patient and the need for person-centred care interventions: “*We should do all we can to encourage healthy interaction between family and patient*” (Nurse 11).

Many of the nurses, however, were also mindful that family members' involvement should occur within set boundaries and not "*overburden them*" (Nurse 10) as "*we [nurses] should be caring for the families more than the patients almost*" (Nurse 7).

Nurses were positive towards the three aspects of the intervention, with the bringing in of personal photographs, glasses and hearing aids described as a "*good idea*" (Nurse 8), and interactions between family members and the patient "*encouraged*" (Nurse 11).

When considering the barriers to family member involvement, nurses identified the following: families' fear, which was in relation to fear of hurting the patient and also being "*uncomfortable*" (Nurse 5) or "*overwhelmed*" (Nurse 11) in a clinical environment; negative nurse attitudes, which related to the perception of the family as an impediment to delivering patient care: *Nurses are stressed with delivering the patient's cares when the family are in the road*" (Nurse 7); and the physical ICU environment: "*[it's] hard sometimes when [the] patient is getting tests done. ICU treatment can be a barrier: [patient] turns, doctors' review, assessments, examinations*" (Nurse 12).

Effect size estimates

The prevalence of ICU delirium in the pre-randomisation (50%), intervention (59%) and non-intervention (56%) groups was comparable and non-statistically different ($p=0.87$, $p=0.98$). When analysing only those participants who were deemed "active" during the study (by completing at least one days' worth of data slips), delirium prevalence rates were again comparable and non-statistically significant ($p=0.80$), although the rate in the intervention group was slightly lower (50%) than the non-intervention group (54%) (Table 3).

The number of days of delirium whilst in ICU was also similar between the groups, with both experiencing a median of one day of delirium ($p=0.60$). Such a non-statistical difference was also observed when analysing the study ‘active’ participants ($p=0.97$) (Table 3).

When including all randomised participants, and using the means and standard deviations of the intervention ($M=1.34$; $SD=1.57$) and control groups ($M=1.03$; $SD=1.12$) for the number of delirium days whilst in ICU, the effect size for a Cohen’s d is 0.23. With a power of 0.80 and probability level of 0.05, a cautious estimate for a future study could need a minimum total sample of $n=596$ ($n=298$ in the intervention and non-intervention groups respectively).

DISCUSSION

To the best of our knowledge this is the first study involving a multicomponent family delivered intervention aimed at reducing delirium within a general ICU population. Importantly, the intervention was founded on existing research in which a similar intervention with families reduced delirium in older adults in general wards (Medical Research Council, 2010; Rosenbloom-Brunton et al., 2010). It was intended to provide initial data to inform the appropriateness of designing a larger RCT.

In terms of feasibility of recruitment, the study was hindered by a relatively low participant recruitment rate (28%), with the majority of exclusions a result of insufficient study personnel to recruit participants. It is likely that limited Research Nurse hours (7:00am to 3:30pm, Monday to Friday with some periods working in a clinical role to support unit demands) resulted in missed opportunities to meet with many eligible patients and their family members, as many visited during the evenings, after work, and at weekend. Alongside this, patients also had to be able to be screened

for delirium, which often meant recruitment could not occur for some days, as evidenced by enrolment taking a median of five days from admission. Studies examining delirium in ICU patients with similar acuity will also experience this recruitment delay, as delirium assessment requires the patient to be responsive to CAM-ICU items.

Reducing the likelihood of intervention cross-contamination is important. Family members in the non-intervention group may have seen what others were doing in the intervention group and copied activities, such as bringing in photographs from home and personalising the bedside. Controlling for contamination of groups is a challenge in ICU research, as families and patients are typically in close proximity to each other, as are the family members in the waiting room. Monitoring what is occurring in practice in future studies would be important. Conducting a cluster RCT is a way to manage possible contamination.

Regarding the acceptability of the intervention, whilst the retention of family members through the study was excellent, consistent delivery of the intervention appeared poor according to our documentation slips. Family members did not report that they thought changes should be made to the intervention, but rather that completing the data slips was sometimes onerous. It may have been the case that family members performed components of the intervention but failed to record it. This highlights the need for examining alternate methods for data collection to promote accuracy. It may be feasible for direct care nurses to record the protocol activities performed by the family members, which may have the added advantage of promoting family member/nurse interactions, facilitating communication (Hwang et al., 2014; Jacobowski et al., 2010), engagement, and continuity of care (Reeves et al., 2015). Such nurses/ family collaboration on aspects of the intervention may also

enhance the effect. In additions, family members with a relative in ICU could be invited to participate in a focus group to better understand user acceptability.

Previous authors suggest that the success of multicomponent interventions to reduce delirium is closely related to the degree of protocol adherence (Inouye, Bogardus, Williams, Leo-Summers, & Agostini, 2003) and recording on the data slips was poor in our study. Adherence may be improved if direct care nurses perform the intervention if the family member is not present.

Limitations

The study was conducted in one adult ICU, which limits wider generalisability. As delirium may manifest quite early in an ICU stay, recruiting patients expected to remain in ICU > 4 days was a limitation. Future studies should recruit ICU patients irrespective of their length of stay. There was no ongoing control over how family members implemented the intervention and upheld intervention fidelity. Future studies should closely monitored treatment fidelity, along with documentation of the activities performed.

CONCLUSION

This single centre feasibility RCT was able to recruit, randomise, and retain family member participants. For higher recruitment rates, Research Nurse hours need to extend into the evening and over the weekend, and further strategies are required to increase protocol adherence and data collection by enlisting the support of the direct care nurses. The nurses were supportive of all aspects of the intervention and did not report significant barriers in this ICU setting. Family members were seen as important care partners, and their involvement afforded many positive outcomes for the ICU

patient and for themselves. However, clinicians should be mindful that families are also a focus of care, alongside the patient, and any involvement should occur at a level/frequency best suited to the family member and, moreover, have no adverse impact upon them or the relationship with the patient.

Acknowledgement

The authors acknowledge the study's Research Nurse Krista Wetzig, for her diligence and sensitivity in the recruitment of patients/family members and data collection at the research hospital site.

Funding

This work was supported by the Centre of Research Excellence in Nursing, and the Centre for Health Practice Innovation at Griffith University.

Conflict of Interest: The authors have no conflict of interest to declare.

REFERENCES

- Al-Mutair AS, Plummer V, O'Brien A, Clerehan R. Family needs and involvement in the intensive care unit: a literature review. *J Clin Nurs* 2013; 22(13-14):1805-17.
- Arnold DM, Burns KE, Adhikari NK, Kho ME, Meade MO, Cook DJ. The design and interpretation of pilot trials in clinical research in critical care. *Crit Care Med* 2009; 37(Suppl 1):69-74.
- Bergbom I, Askwall A. The nearest and dearest: a lifeline for ICU patients. *Intensive Crit Care Nurs* 2000; 16(6):384-95.
- Brummel NE, Girard TD. Preventing delirium in the intensive care unit. *Crit Care Clin* 2013; 29(1):51-65.
- Brummel NE, Jackson JC, Pandharipande PP, Thompson JL, Shintani AK, Dittus RS, Gill TM, Bernard GR, Ely EW, Girard TD. Delirium in the ICU and subsequent long-term disability among survivors of mechanical ventilation. *Crit Care Med* 2014; 42(2):369-77.
- Ely EW, Inouye SK, Bernard GR, Gordon S, Francis J, May L, Truman B, Speroff T, Gautam S, Margolin R, Hart RP, Dittus R. Delirium in mechanically ventilated patients: validity and reliability of the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU). *J Am Med Assoc* 2001a; 286(21):2703-10.
- Ely EW, Margolin R, Francis J, May L, Truman B, Dittus R, Speroff T, Gautam S, Bernard GR, Inouye SK. Evaluation of delirium in critically ill patients: validation of the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU). *Crit Care Med* 2001b; 29(7):1370-9.
- Ely EW, Shintani A, Truman B, Speroff T, Gordon SM, Harrell FE, Jr., Inouye SK, Bernard GR, Dittus RS. Delirium as a predictor of mortality in mechanically

- ventilated patients in the intensive care unit. *J Am Med Assoc* 2004; 291(14):1753-62.
- Ely EW, Truman B, Shintani A, Thomason JW, Wheeler AP, Gordon S, Francis J, Speroff T, Gautam S, Margolin R, Sessler CN, Dittus RS, Bernard GR. Monitoring sedation status over time in ICU patients: reliability and validity of the Richmond Agitation-Sedation Scale (RASS). *J Am Med Assoc* 2003; 289(22):2983-91.
- Girard TD, Jackson JC, Pandharipande PP, Pun BT, Thompson JL, Shintani AK, Gordon SM, Canonico AE, Dittus RS, Bernard GR, Ely EW. Delirium as a predictor of long-term cognitive impairment in survivors of critical illness. *Crit Care Med* 2010; 38(7):1513-20.
- Hertzog, M. A. Considerations in determining sample size for pilot studies. *Research in Nursing and Health* 2008; 31(2):180-91.
- Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, Altman DG, Barbour V, Macdonald M, Lamb SE, Dixon-Woods M, McCulloch P, Wyatt JC, Chan A-W, Michie S. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014; 348:g1687. [doi:10.1136/bmj.g1687](https://doi.org/10.1136/bmj.g1687)
- Holroyd-Leduc JM, Khandwala F, Sink KM. How can delirium best be prevented and managed in older patients in hospital? *Can Med Assoc J* 2010; 182(5):465-70.
- Hsieh TT, Yue J, Oh E, Puelle M, Dowal S, Trivison T, Inouye SK. Effectiveness of multicomponent nonpharmacological delirium interventions: a meta-analysis. *JAMA Intern Med* 2015; 175(4):512-20.
- Hwang DY, Yagoda D, Perrey HM, Tehan TM, Guanci M, Ananian L, Currier P.F., Cobb J, Rosand J. Consistency of communication among intensive care unit

- staff as perceived by family members of patients surviving to discharge. *J Crit Care* 2014; 29:134-8.
- Inouye SK, Baker DI, Fugal P, Bradley EH. Dissemination of the hospital elder life program: Implementation, adaptation, and successes. *J Am Geriatr Soc* 2006; 54(10):1492-9.
- Inouye SK, Bogardus ST, Jr., Baker DI, Leo-Summers L, Cooney LM, Jr. The Hospital Elder Life Program: a model of care to prevent cognitive and functional decline in older hospitalized patients. *Hospital Elder Life Program. J Am Geriatr Soc* 2000; 48(12):1697-706.
- Inouye SK, Bogardus ST, Jr., Charpentier PA, Leo-Summers L, Acampora D, Holford TR, Cooney LM, Jr. A multicomponent intervention to prevent delirium in hospitalized older patients. *The New England Journal of Medicine* 1999; 340(9):669-76.
- Jacobowski NL, Girard TD, Mulder JA, Ely EW. Communication in critical care: family rounds in the intensive care unit. *Am J Crit Care* 2010; 19:421-30.
- Kean S, Mitchell M. How do ICU nurses perceive families in intensive care? Insights from the United Kingdom and Australia. *J Clin Nurs* 2014; 23(5-6):663-72.
- Lat I, McMillian W, Taylor S, Janzen JM, Papadopoulos S, Korth L, Ehtisham A, Nold J, Agarwal S, Azocar R, Burke P. The impact of delirium on clinical outcomes in mechanically ventilated surgical and trauma patients. *Crit Care Med* 2009; 37(6):1898-905.
- Martinez F, Tobar C, Hill N. Preventing delirium: should non-pharmacological, multicomponent interventions be used? A systematic review and meta-analysis of the literature. *Age Ageing* 2015; 44(2):196-204.

- Martinez FT, Tobar C, Beddings CI, Vallejo G, Fuentes P. Preventing delirium in an acute hospital using a non-pharmacological intervention. *Age Ageing* 2012; 41(5):629-34.
- McKinley S, Fien M, Elliott R, Elliott D. Health related quality of life and associated factors in intensive care unit survivors 6 months after discharge. *Am J Crit Care* 2016; 2552-8.
- Medical Research Council. (2010). Developing and evaluating complex interventions: new guidance. Retrieved March 24th 2016, from <https://http://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/>.
- Milbrandt EB, Deppen S, Harrison PL, Shintani AK, Speroff T, Stiles RA, Truman B, Bernard GR, Dittus RS, Ely EW. Costs associated with delirium in mechanically ventilated patients. *Crit Care Med* 2004; 32(4):955-62.
- Mitchell M, Chaboyer W, Burmeister E, Foster M. Positive effects of a nursing intervention on family-centered care in adult critical care. *Am J Crit Care* 2009; 18(6):543-52.
- Mitchell ML, Chaboyer W. Family Centred Care - a way to connect patients, families and nurses in critical care: a qualitative study using telephone interviews. *Intensive Crit Care Nurs* 2010; 26(3):154-60.
- Pandharipande PP, Girard TD, Jackson JC, Morandi A, Thompson JL, Pun BT, Brummel NE, Hughes CG, Vasilevskis EE, Shintani AK, Moons KG, Geevarghese SK, Canonico A, Hopkins RO, Bernard GR, Dittus RS, Ely EW. Long-term cognitive impairment after critical illness. *N Engl J Med* 2013; 369(14):1306-16.
- Reeves S, McMillan SE, Kachan N, Paradis E, Leslie M, Kitto S. Interprofessional collaboration and family member involvement in intensive care units: emerging

- themes from a multi-sited ethnography. *Journal of Interprofessional Care* 2015; 29(3):230-7.
- Roberts B, Rickard CM, Rajbhandari D, Turner G, Clarke J, Hill D, Tauschke C, Chaboyer W, Parsons R. Multicentre study of delirium in ICU patients using a simple screening tool. *Aust Crit Care* 2005; 18(1):6-16.
- Rosenbloom-Brunton DA, Henneman EA, Inouye SK. Feasibility of family participation in a delirium prevention program for hospitalized older adults. *J Gerontol Nurs* 2010; 36(9):22-33.
- Sessler CN, Gosnell MS, Grap MJ, Brophy GM, O'Neal PV, Keane KA, Tesoro EP, Elswick RK. The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care unit patients. *Am J Respir Crit Care Med* 2002; 166(10):1338-44.
- Thorne S. Interpretive description. In: Beck CT, editors. *Routledge international handbook of qualitative nursing research*. Abingdon: Routledge; 2013. P. 295 - 306.
- Inouye SK, Bogardus ST Jr, Williams CS, Leo-Summers L, Agostini JV. The role of adherence on the effectiveness of nonpharmacologic interventions: evidence from the delirium prevention trial. *Arch Intern Med* 2003; 163(8); 958-64
DOI:10.1001/archinte.163.8.958

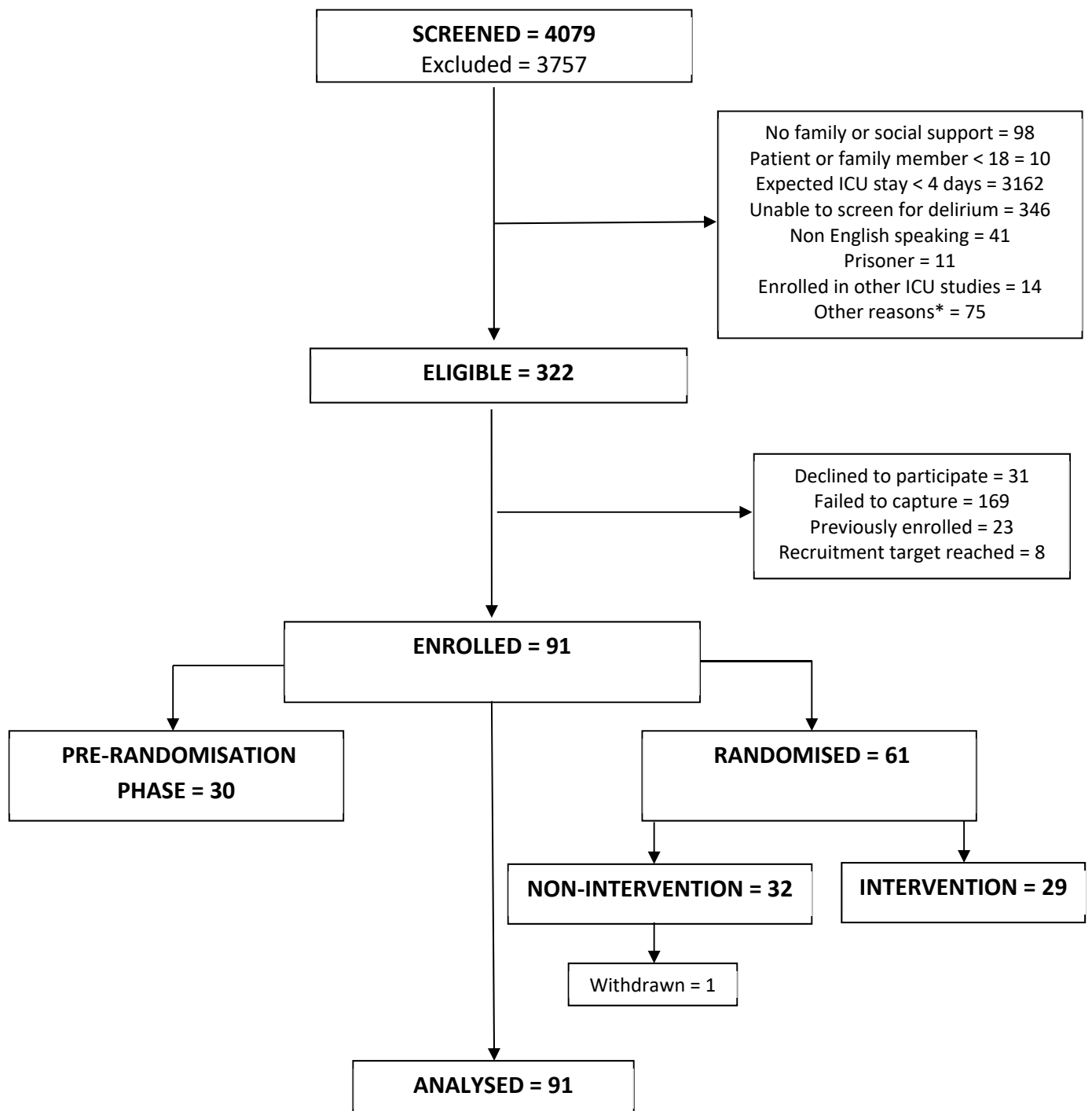


Figure 1 Participant flow through the study

Note. *Other reasons = Ineligible (other) includes: patients non-compliant (e.g. refusal towards cares and Confusion Assessment Method for the Intensive Care Unit participation); palliated; underlying physical/mental disability; Traumatic Brain Injury resulting in fluctuating Glasgow Coma Scale and patient "uncooperative" in participation; difficult relationships with family members; partner was blind and unable to fill out forms; encephalopathic; hostile towards staff and poor relationships and previously declined other studies; attempts to speak to family but unable to get them to converse with staff (e.g. too distracted by patient in bed).

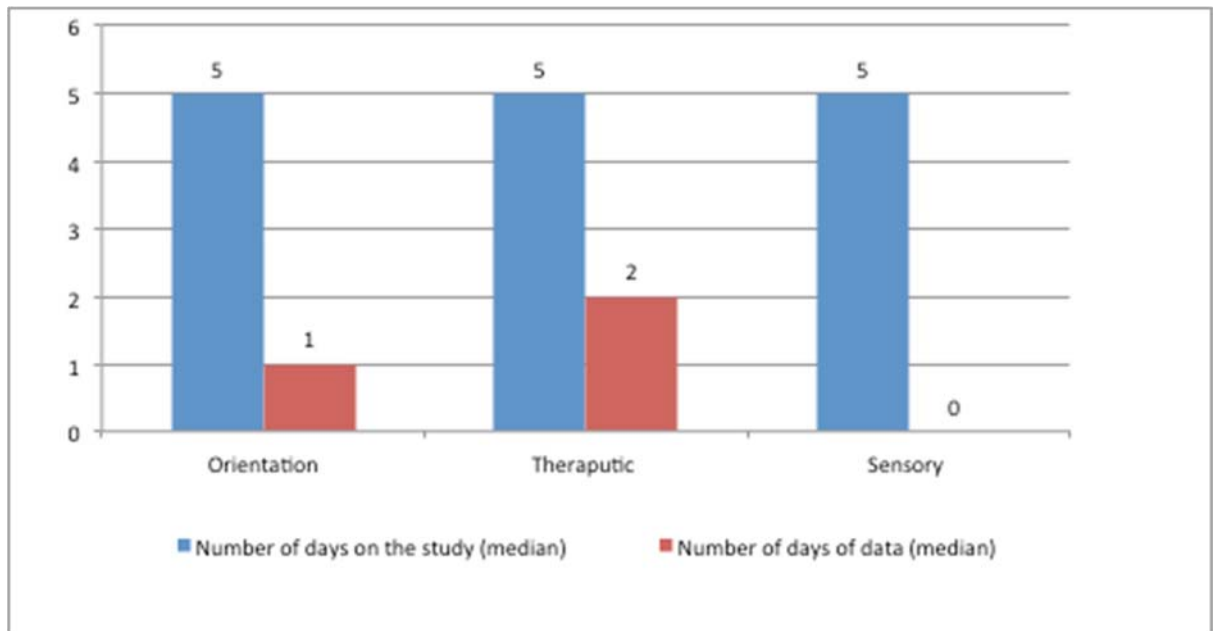


Figure 2 Median days on the study compared with median days of data for the three protocols

Table 1 Baseline demographic and clinical characteristics of all enrolled patient participants in the pre-randomisation, control and intervention groups

Characteristic	Pre- randomisation (<i>n</i> =30)	Control (<i>n</i> =32) ¹	Intervention (<i>n</i> =29)	<i>p</i> - value
Age (years)	54.0 (32) ^a	60.0 (21) ^a	52.0 (32) ^a	0.29
Sex (male)	20 (66.7%)	20 (62.5%)	20 (69.0%)	0.86
Marital status:				0.95
Married/De facto	16 (53.3%)	18 (56.3%)	16 (55.2%)	-
Never married	8 (26.7%)	6 (18.8%)	7 (24.1%)	-
Single	3 (10.0%)	6 (18.8%)	2 (6.9%)	-
Widowed	3 (10.0%)	2 (6.3%)	3 (10.3%)	
Admission diagnosis:				0.39
Medical	17 (56.7%)	12 (37.5%)	14 (48.3%)	-
Surgical	6 (20.0%)	5 (15.6%)	6 (20.7%)	-
Trauma	7 (23.3%)	15 (46.9%)	9 (31.0%)	-
APACHE II score ^b	19.0 (10) ^a	21.0 (8) ^a	18.0 (13) ^a	0.83
APACHE III score ^c	65.0 (36) ^a	52.5 (42) ^a	61.0 (41) ^a	0.81
Length of stay in ICU (days)	9.8 (6.20) ^a	10.5 (11) ^a	10.0 (7.82) ^a	0.73
Length of stay in hospital (days)	28.2 (23.32) ^a	36.5 (24.80) ^a	26.6 (16.15) ^a	0.65
Mechanical ventilation in ICU:				
Prevalence	29 (96.7%)	31 (96.9%)	29 (100%)	0.62
Days	7.5 (7) ^a	10.0 (10) ^a	9.0 (7) ^a	0.26

All results are presented as *n* (%) or median (Interquartile Range) as indicated. Frequencies and proportions may not add up to group totals (Pre-randomisation *n*=30, Control *n*=32 [includes 1 participant who withdrew from the study], Intervention *n*=29), and 100% due to missing data or rounding.

APACHE = Acute Physiology and Chronic Health Evaluation, ICU = Intensive Care Unit.

¹All enrolled participants, including 1 withdrawn participant

^aMedian (Interquartile Range)

^bAPACHE II scores range 0 – 71 with higher scores indicating more severe disease

^cAPACHE III scores range 0-299 with higher scores indicating more severe disease.

Table 2 Baseline characteristics of family members with participants enrolled in the control and intervention groups

Characteristic	Control (<i>n</i> =32) ¹	Intervention (<i>n</i> =29)	<i>p</i> -value
Age (years)	54.5 (22) ^a	51.0 (22) ^a	0.47
Sex (male)	9 (28.1%)	8 (27.6%)	0.96
Relationship to participant:			0.52
Partner/Spouse	17 (53.1%)	13 (44.8%)	-
Mother	4 (12.5%)	5 (17.2%)	-
Father	1 (3.1%)	3 (10.3%)	-
Son	3 (9.4%)	2 (6.9%)	-
Daughter	5 (15.6%)	5 (17.2%)	-
Sister	0 (0.0%)	1 (3.4%)	-
Friend	1 (3.1%)	0 (0.0%)	-
Education level:			0.13
Primary or less	1 (3.1%)	1 (3.4%)	-
Secondary	13 (40.6%)	13 (44.8%)	-
Certificate or Diploma	5 (15.6%)	11 (37.9%)	-
University: Undergraduate/Bachelor	6 (18.8%)	3 (10.3%)	-
University: Grad. Diploma/Certificate	0 (0.0%)	1 (3.4%)	-
University: Postgraduate	3 (9.4%)	0 (0.0%)	-
Marital status:			0.21
Married/De facto	28 (87.5%)	22 (75.9%)	-
Never married	1 (3.1%)	1 (3.4%)	-
Single	1 (3.1%)	4 (13.8%)	-
Widowed	1 (3.1%)	1 (3.4%)	-

All results are presented as *n* (%) or median (Interquartile Range) as indicated. Frequencies and proportions may not add up to group totals (Control *n*=32 [includes 1 participant who withdrew from the study], Intervention *n*=29), and 100% due to missing data or rounding.

Grad. = Graduate

¹All enrolled participants, including 1 withdrawn participant

^aMedian (Interquartile Range).

Table 3 Prevalence and duration of patient delirium whilst in ICU

Delirium in ICU	All patient participants			
	Overall (<i>n</i>=91)	Control (<i>n</i>=32)¹	Intervention (<i>n</i>=29)	<i>p</i>-value
Prevalence	50 (55%)	18 (56%)	17 (59%)	<i>p</i> =0.85
Days	1.0 (2) ^a	1.0 (2) ^a	1.0 (2) ^a	<i>p</i> =0.60
Patient participants who had ≥1 data slips completed				
	Overall (<i>n</i>=50)²	Control (<i>n</i>=28)¹	Intervention (<i>n</i>=22)	<i>p</i>-value
Prevalence	26 (52%)	15 (54%)	11 (50%)	<i>p</i> =0.80
Days	1.0 (2) ^a	1.0 (2) ^a	0.5 (2) ^a	<i>p</i> =0.97

All results are presented as *n* (%), or median (Interquartile Range) as indicated. Frequencies and proportions may not add up to group totals, and 100% due to missing data or rounding.

ICU = Intensive Care Unit

¹All enrolled participants, including 1 withdrawn participant

²Considered active if there were one or more days' data slips completed over the course of the study is recorded from control and intervention groups

^aMedian (Interquartile Range)

Appendix A: Intervention description using the template for intervention description and replication (TIDieR) checklist (Hoffman et al., 2014)

Item 1. Brief name: Provide the name or a phrase that describes the intervention

Orientation, therapeutic engagement and sensory checks by family members.

Item 2. Why: Describe any rationale, theory, or goal of the elements essential to the intervention

Addressing modifiable patient risk factors for delirium, such as orientation and appropriate sensory stimulation, may assist in the prevention and reduction of delirium incidence and duration in the ICU. Multicomponent interventions have been successfully developed to achieve this with hospitalised non-ICU older patients (Brummel & Girard, 2013; Holroyd-Leduc et al., 2010; Hsieh et al., 2015; Inouye et al., 2000; Inouye et al., 1999; Martinez et al., 2015). Whilst the majority of these have been delivered by nursing staff, a small number have also demonstrated the potential efficacy of family members delivering similar interventions to their relative (Martinez et al., 2012; Rosenbloom-Brunton et al., 2010).

The orientation, therapeutic engagement and sensory checks are designed to be delivered by the patient's family member who has intimate knowledge of what and how to engage their relative in a meaningful way.

Item 3. What (materials): Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers.

- 4) Educational materials for families and staff in regards to each component of the protocol
- 5) Orientation materials – white-board day planner for the patient's bed area; meaningful family photographs for the bedside area
- 6) Family to bring in relative's working hearing aids and/ or glasses

Item 4. What (procedures): Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.

Participant families and direct care nurses were provided information and on-going education by the research nurse around the 3 components of the intervention which were to occur daily. Two components (orientation and therapeutic engagement) were

compulsory and the third (sensory) was delivered if applicable. Intensive training was provided one-on-one to direct care nurses with ongoing support during the trial in the three components as outlined:

1) Orientation component: (a) white-board day planner in situ and updated by the direct care nurse with their and the doctor's name for that day, and the plan of care that day; (b) family were asked to bring in meaningful family photographs for the bedside area. Family members were instructed at each visit by the research nurse on: (1) Orientation: how to orientate the patient to their surroundings including where they were and why, and the day, date, and time; (2) Therapeutic engagement – to speak about current family life events and reminisce on events of known interest to the patient; (3) Sensory – to check that their relative had their glasses on and hearing aids in place/working to ensure/promote the ability to communicate (if applicable). The data collection slips [positioned at each bed space] where family members recorded the 3 components, provided an additional prompt to family members.

Item 5. Who provided: For each category of intervention provider (for example, psychologist, nursing assistant), describe their expertise, background and any specific training given

The research nurse (bachelor degree and post graduate qualification in critical care nursing) provided ongoing education to family members who provided all aspects of the intervention.

Item 6. How: Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group

The 3 components of the intervention were delivered face-to-face at the bed-side by the family member when they visited their relative in ICU.

Item 7. Where: Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features

The intervention occurred at patients' bed space in a public 25-bed adult tertiary referral teaching hospital. The model of care is a ratio of one-to-one nurse/patient ratio. Patient

rooms varied from some who were in single room and others were separated from the next door patient by partial walls and curtains.

Item 8. When and how much: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose

The intervention was designed to be delivered by the family member each day that they visited their relative. If they stayed for prolonged periods, they could select when they wanted to deliver the intervention components. The direct care nurses may guide as to the most appropriate time depending on the need for the patient to sleep.

Item 9. Tailoring: If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how

Each patient had the intervention delivered by their own family member, thus they experienced a completely individualised intervention in relation to its content. Those patients who did not have sensory impairments [i.e. need for glasses or hearing aids] would not have needed this component of the intervention.

Item 10. Modifications: If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)

There were no modifications made to the protocol during the course of the study.

Item 11. How well (planned): If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them

Intervention fidelity was assessed by examination of the completed paper data collection slips at the bed-side. Individual education sessions were provided to family to improve intervention fidelity.

Item 12: How well (actual): If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

Three-quarters of family members (76%) in the intervention group and 87% of the non-intervention group completed at least one data slip. In relation to the intervention

group the proportion completing data slips for each of the intervention activities was: therapeutic activities, 35%; orientation, 30%, and, sensory checks 20%.