Intensive and Critical Care Nursing xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Intensive and Critical Care Nursing

journal homepage: www.elsevier.com/iccn

Clinical research article

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

Marion L. Mitchell[a,b,c,d,*], Susanne Kean[e], Janice E. Rattray[f], Alastair M. Hull[g,h], Chelsea Davis[d], Jenny E. Murfield[b,c], Leanne M. Aitken[a,b,c,d,i]

[a] NHMRC Centre for Research Excellence in Nursing, Griffith University, Nathan Campus, Brisbane, Queensland, Australia
[b] Menzies Health Institute Queensland, Griffith University, Nathan Campus, Brisbane, Queensland, Australia
[c] School of Nursing and Midwifery, Griffith University, Nathan Campus, Brisbane, Queensland, Australia
[d] Princess Alexandra Hospital Intensive Care Unit, Princess Alexandra Hospital, Brisbane, Queensland, Australia
[e] School of Health in Social Science, University of Edinburgh, Edinburgh, UK
[f] School of Nursing and Health Sciences, University of Dundee, Dundee, UK
[g] Perth Royal Infirmary, NHS Tayside, Dundee, UK
[h] Department of Psychiatry, University of Dundee, Dundee, UK
[i] School of Health Sciences, City University London, London, UK

ARTICLE INFO

*Article history:*
Accepted 1 January 2017

*Keywords:*
Critical illness
Delirium
Families
Family-centred care
Feasibilities studies
Health care
Intensive care units
Nursing
Person-centred care

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.


## 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

* Corresponding author at: School of Nursing and Midwifery, Health Sciences Building (N48), 170 Kessels Road, Nathan, Queensland 4111, Australia.
*E-mail addresses:* marion.mitchell@griffith.edu.au (M.L. Mitchell), Susanne.Kean@ed.ac.uk (S. Kean), j.z.rattray@dundee.ac.uk (J.E. Rattray), ahull@nhs.net (A.M. Hull), Chelsea.Davis@health.qld.gov.au (C. Davis), j.murfield@griffith.edu.au (J.E. Murfield), Leanne.Aitken.1@city.ac.uk (L.M. Aitken).

http://dx.doi.org/10.1016/j.iccn.2017.01.001
0964-3397/

**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: 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.

date, various multicomponent interventions have been successfully developed to achieve this with hospitalised non-ICU older patients (Brummel and Girard, 2013; Holroyd-Leduc et al., 2010; Hshieh et al., 2015; Inouye et al., 2000, 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 and 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 and Mitchell, 2014; Mitchell et al., 2009), and feel more useful and physically and emotionally close to their relative (Mitchell and 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 randomised controlled trial (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, 2000, 1999; Rosenbloom-Brunton et al., 2010) and in this study included three components with components one (orientation) and two

Please cite this article in press as: Mitchell, M.L., et al., A family intervention to reduce delirium in hospitalised ICU patients: A feasibility randomised controlled trial. Intensive Crit Care Nurs (2017), http://dx.doi.org/10.1016/j.iccn.2017.01.001