Study Protocol of a Randomised Controlled Group Trial of Client and Care Outcomes in the Residential Dementia Care Setting

Lynn Chenoweth, RN, Cert Burns/Plastic Surg, Dip Leis, BA, MA(Hons), M Ad Ed, GD Tch/Lrn, PhD, Madeleine King, BSc, Dip Stats, Grad Dip Med Stats, PhD, Georgina Luscombe, BPsy(Hons), PhD, Ian Forbes, BArch, MSc, GradDipBus, Yun-Hee Jeon, RN, DN, BHScN, MN, PhD, Jane Stein-Parbury, RN, BSN, MD, PhD, FRCPA, Yun-Hee Jeon, RN, DN, BHScN, MN, PhD, Jane Stein-Parbury, RN, BSN, MD, PhD, FRCPA, Yun-Hee Jeon, RN, DN, BHScN, MN, PhD, Georgina Luscombe, BPsy(Hons), PhD, Ian Forbes, BArch, MSc, GradDipBus, Yun-Hee Jeon, RN, DN, BHScN, MN, PhD, Georgina Luscombe, BPsy(Hons), PhD, Ian Forbes, BArch, MSc, GradDipBus, Yun-Hee Jeon, RN, DN, BHScN, MN, PhD, Jane Stein-Parbury, RN, BSN, MD, PhD, FRCPA, Richard Fleming, BTech(Hons), DCL.Psy, Marion Haas, BPhty(Qld), MPH, PhD(Syd)

ABSTRACT

Purpose: Literature suggests that quality of life (QOL), quality of care (QOC) and Behavioural and Psychological Symptoms of Dementia (BPSD) can be improved by relatively simple and inexpensive person-centred approaches to nursing care practices (PCC) and modifications to physical environment (PCE). Most research on this topic is observational and few randomised controlled trials have included an economic evaluation of PCC and PCE together. The PerCEN study aims to confirm the value of evidence-based nursing by evaluating the efficacy and cost effectiveness of implementing PCC and PCE in residential dementia care services. This article describes the PerCEN study protocol (ANZCTR 12608000095369).

Design/Methods: The 3-year study commenced in 2009 in 38 eligible government-accredited residential dementia care homes in New South Wales, Australia. Study participants include 605 consented residents over 60 years of age with dementia and 380 consenting permanent direct-care staff. The study employs a factorial, group-randomised, cohort design with stratification to evaluate the main effects of PCC and PCE and their joint effects (PCC + PCE), compared with Usual Care (UC) and Usual Environment (UE) on QOL, QOC and BPSD in dementia.

Results: The primary outcomes analysis will use a mixed-model analysis of covariance to determine the effects of PCC and PCE on resident QOL and BPSD, and QOC, adjusting for stratification and other potential confounders. The incremental cost of providing PCE and PCC over UC and UE will be calculated; costs and outcomes will be presented as a cost-consequence analysis and cost-effectiveness ratios will be estimated as a cost per unit change in resident QOL and BPSD.

Implications: This cluster-randomised trial will rigorously test Kitwood's Social-Psychological Theory of Personhood in Dementia (Kitwood & Bredin 1992). The results will provide timely and solid evidence that can inform policy and nursing practice development in improving the person's QOL and QOC, and reducing BPSD.

KEYWORDS dementia, aged care residents, behavioural and psychological symptoms of dementia, quality of care, quality of life, practice development, person centredness

All the Chief Investigators and Associate Investigators were independent researchers, funded by their respective academic institutions and not by the funding body and no drug involvement was trailed. Trial registration ACTRN12608000095369.

Address correspondence to Lynn Chenoweth, PO Box 222, Lindfield, NSW 2070, Australia; Lynnette.Chenoweth@uts.edu.au

Accepted 4 August 2010
Copyright ©2010 Sigma Theta Tau International
doi: 10.1111/j.1741-6787.2010.00204.x
INTRODUCTION

There can be no greater need for people with dementia, when moving to permanent residential care, than achieving the best possible quality of life (QOL) and receiving optimal quality of care (QOC). Achieving QOL and QOC in dementia are recognised as two of the Australian government health and aged care research priorities (Commonwealth of Australia 2004; Rees 2005/6). The progressive nature of dementia leads to a significant reduction in capacity for self-care and self-determination, which are essential features of QOL. Kitwood’s Social-Psychological Theory of Personhood in Dementia (Kitwood & Bredin 1992) challenges the notion that dementia must inevitably be characterised by decline, disintegration and despair. The theory posits that ill-being, or poor QOL, may result from negative contextual stimuli, including physical environments that lack cues to orient the person to their present reality, and nursing care practices that disregard “personhood” by denying opportunities for making choices and decisions (Kitwood 1997). Provision of Person-Centred Care (PCC) and Person-Centred Environment (PCE) is underpinned by Kitwood’s theory.

Person-Centred Care

PCC is an evidence-based care model most commonly applied in aged and dementia care, but suitable for use in all health contexts (Brooker 2004). It is distinguished by care that focuses on making genuine efforts to understand and respect the person’s individuality, making contact with the person to understand their present world, meeting the person’s individual needs for love and comfort, supporting their remaining strengths, recognising, respecting and valuing the person’s individuality and strengths, rather than their weaknesses. Striving to achieve these goals will place the person with dementia in the best possible position to achieve a sense of place and belonging within their social and material world (Kitwood 1997; Coyle & Williams 2001; Ericson et al. 2001). When staff members do not focus on supporting personhood as described, Behavioural and Psychological Symptoms of Dementia (BPSD) can arise, often from restraint practices or staff’s unwitting neglect of the person’s psychosocial needs. This more task-focused care can lead to function loss and social alienation; comprising what Kitwood (1997) termed “malignant social psychology.” The usual type of nursing care occurring in many residential aged care homes focuses on supporting the individual’s medical needs and physical aspects of activities of daily living, to the neglect of the person’s unique psychosocial needs. Hence, implementing a non-person-centred, biomedical model of care in the residential care setting, leads to long, lonely hours alone, little engagement with staff members in social exchange, few opportunities for personally meaningful activities and emotional distress (Chenoweth et al. 2009). On the other hand, PCC sees staff focusing on therapeutic relationships and effective communication with the person, providing care in a caring and respectful way, encouraging and allowing choices and personal decision-making in all aspects of daily life and providing many opportunities for enriched life experiences (Kitwood & Bredin 1992). We see evidence of PCC occurring through a decrease in the person’s incidence and severity of ill-being; a decrease in BPSD such as agitation, anxiety, anger, aggression and perseveration; and an increase in the person’s levels of well-being (Cohen-Mansfield et al. 2007).

Person-Centred Environment

A PCE can serve as a nonpharmacological supportive element in retaining memory, stimulating the remaining senses, enabling therapeutic communication with carers, assisting the person to retain self-control and reducing levels of anxiety, aggression, depression and psychotic behaviour, through built “cues” (Zeisel et al. 2003; Fleming et al. 2005). A PCE improves, or slows the decline in, residents’ communication skills, self-care skills, social function, mobility and affective responses and reduces behavioural disturbances, abnormal motor activity, apathy and hallucinations (Day et al. 2000). The physical environment can therefore exercise dramatic psychological impact on QOL for persons with dementia through supporting their personhood. This enables better self-control and independence. Evidence of a PCE is observed when the care setting is: (1) safe and secure, small and familiar, simple and domestic in design, has good visual access, reduces levels of unwanted stimulation and enhances levels of helpful stimulation; (2) allows for wandering, facilitates independence and choice, provides opportunities for both privacy and community; and (3) has links to the community (Swanson et al. 1993; Day et al. 2000). Further evidence of PCE may be the environmental capacity to enhance QOL by supporting personal strengths, reducing unnecessary demands on areas of limitation and supporting staff’s ability to provide QOC (Fleming et al. 2005).

With the increasing demands being placed on residential dementia services and nurses to achieve quality of care, it is essential that managers have access to evidence-based care approaches when choosing the model most suited to the needs of their residents and direct-care staff. Without evaluating the efficacy of dementia care models, money and other resources can be wasted on expensive and ineffective approaches that are not based on good evidence,
DESIGN AND METHODS

We employed a factorial group-randomised cohort study with stratification to evaluate the main effects of PCC and PCE and in their joint effects on resident outcomes and care delivery. The CADRES study (Chenoweth et al. 2009) indicated considerable correlation within individuals over time (range 0.6–0.7), so a cohort design (pretest, posttest and follow-up) increases the power of the design. Stratification ensures balance across treatment groups on geographical locale and type of facility (private for profit, private not for profit), allowing us to test whether the effects of PCC and PCE differ across strata (a policy-relevant question). Other potential confounders, such as care programs/education and building or design works that might occur in UC sites during the trial, will be adjusted for in the analysis to improve precision and limit bias due to selection and other factors. Participating residential care facilities have been allocated randomly to one of four treatment groups, with two treatment factors each having two levels:

1. **PCC:**
   - Level 1: PCC delivery according to Kitwood’s care principles (PCC)
   - Level 2: usual (non-person-centred) care (UC).

2. **PCE:**
   - Level 1: adjustments to spatial configurations employing Kitwood’s principles for person-centred dementia environment (PCE)
   - Level 2: usual (non-person-centred) dementia environment (UE)

This factorial design gives four treatment groups: PCE + UC, PCE + PCC, and UE + PCC; and UE + UC (See Figure 1).

Randomisation

To help ensure comparability of the intervention and UC and environment sites with respect to baseline characteristics, sites were matched according to the following criteria: (1) care practice and environmental quality as assessed with the PCE and Care Assessment Tool (PCECAT), comprising 77 items in three domains; (2) organisational culture, care quality and environment quality, range 0 (absent) to 3 (fully present) (Burke et al. n.d.); (3) dementia-specific unit (yes, no); (4) location (inner metropolitan, outer metropolitan, rural); (5) size (number of dementia beds—10–20 beds (small), >20 beds (large); (6) type (profit, not for profit) and (7) organisation (several sites were owned by the same organisation). Matched groups were randomly allocated to the four intervention groups.

The study statisticians (King and Luscombe) generated the allocation sequence, blind to the identity of the site, using an SAS program (1999). Allocation was based on clusters of homes allocated to interventions, rather than individuals, and was concealed from other study team members until interventions were assigned.

Study Setting

Of the 89 eligible residential aged care homes screened, the 38 lowest PCECAT-scoring homes for PCC and PCE were selected, as they were more likely to show improved outcomes in QOL, BPSD and QOC through the study interventions.

**Inclusion criteria.** Included Australian government approved and accredited residential aged/dementia care services providing high care for residents with dementia; accessible by sealed road; located in the Sydney, Newcastle...
Figure 1. PerCEN cluster RCT flow diagram.
and Wollongong regional areas; and in rural NSW within a 300 km radius of the Sydney central business district.

**Exclusion criteria.** Included state-run aged care homes, aged care homes providing the highest levels of PCC and PCE, as assessed initially by the PCECAT (Burke et al. n.d.) and confirmed by the Environment Assessment Tool (EAT) (Fleming et al. 2001).

The 38 care homes included are representative of most other Australian residential dementia care services in the following respects: (1) provide high-care residential service to between 20 and 60 persons with a diagnosed, moderate level of dementia as determined by the Aged Care Funding Instrument (ACFI) (Australian Government, 2008); (2) funded by the Australian government on that basis; (3) meet the Australian residential care accreditation standards (Commonwealth Department of Health and Aged Care 1998) and building certification requirements (Commonwealth of Australia 2003); (4) operate as private for profit or private not for profit (charity and religious); (5) have similar management structures, staffing ratios (1 nurse to 8–10 residents) and staff mix; (6) serviced by general practitioners (GPs) and other specialist health staff and (7) service provision for residents with dementia is very similar (including nursing care, therapy provision and recreation/leisure programs).

**STUDY PARTICIPANTS**

**Sampling Frame**

Dementia care resident sample calculations were based on resident QOL (measured with Dementia QOL, DEMQOL) as the primary outcome measure. The recent RCT of PCC (Chenoweth et al. 2009) provided estimates of: within-resident intraclass correlation (ICC) of 0.6; within-site ICC of 0.07; and relative benefit of PCC versus UC of 8% (we assume the same magnitude of effect for PCE vs. UC). Using the DEMQOL total scale equates to an improvement from baseline to follow-up for PCC or PCE groups of, on average, one category (e.g., from “not at all” to “a little” or from “quite a bit” to “a lot”) on 4 of 28 items, and a deterioration for UC groups of one category on 3 of 28 items. This gives a mean difference in change of 7 points on a scale with a range of 84 points and a standard deviation of 11 (i.e., an effect size of 0.64), which was considered clinically important. Fixing the Type I error rate at 5%, we used these estimates to determine that 40 groups, with 9 residents per group at follow-up, would have 80% power to detect a clinically important difference of 8% in QOL between PCC and UCC at follow-up; and 12 residents per group will have 90% power (Murray 1998). Based on our experience with the pilot studies and the recent PCC RCT (Chenoweth et al. 2009), we expected a dropout rate of 20% to 25% from baseline to follow-up. Thus, we needed to recruit 15 residents per site (600 in total), representing about 60% to 75% of residents with dementia in the selected aged care homes. We also needed to recruit 10 staff per site (400 in total). These sample sizes were considered sufficient for analysis of the secondary outcomes, the process measures and the economic evaluation.

**Residents (N = 605)**

**Inclusion criteria.** Included a permanent stay, consented residents with a medical diagnosis of dementia identified in their medical charts, and classified to require high-care services as assessed by regulated Australian Aged Care Assessment Teams.

**Exclusion criteria.** Included a short stay and non-consented residents with no dementia diagnosis. Residents with serious comorbidities that preclude them from engaging in normal daily activities and social life within the care home and who are unlikely to be able to participate over the life of the study (e.g., florid mental illness, end-stage illness, unremitting pain/distressing physical symptoms) were excluded.

**Residential Care Staff (N = 380)**

**Inclusion criteria.** Included permanent direct-care staff who were employed at the care facility for at least 2 months prior to pretest, including Registered Nurses, Enrolled Nurses, Assistants in Nursing, Personal Care Assistants, diversional therapists, recreation activity officers and allied health staff.

**Exclusion criteria.** Included casual and agency staff.

**Participant Recruitment Procedures**

Prior to participant recruitment, research ethics approval was granted by the University of Technology Sydney (UTS-HREC 2006–269) and the relevant decision-making bodies of the 38 aged care homes. Approval was obtained from the Guardianship Tribunal for residents with no family guardian able to consent on the resident's behalf. To gain resident and family approvals the PerCEN study, project manager and research assistants (RAs) first met with prospective participants in the residential care home, either individually or in small groups. Initially, facility managers identified potential eligible residents and supplied these names to a study team member who was blind to site allocation. Residents considered suitable for inclusion and/or their next of kin/guardian were provided with verbal and large print information in the presence of trusted staff and/or other family members to gain their assent, and where able, resident informed consent to be screened for possible inclusion. In most cases, the family guardian needed to provide proxy consent for residents. Residents and family members unable to speak and...
understand spoken and written English were provided assistance to give consent/assent from bilingual care staff/managers. Resident screening for inclusion then proceeded and written consent was obtained from proxies for those assessed as eligible. Verbal assent was gained from residents during pretest data collection each time the RAs needed to observe and communicate with them. Verbal assent to resident participation was also sought, and in most cases gained, from the resident’s medical practitioner (GP).

Staff members were recruited through site meetings where the researchers explained the study verbally and in writing. Staff unable to read and write English had the opportunity to provide informed consent with the assistance of a nominated staff member of their choice.

Study Interventions
Following pretest data collection at all 38 homes the study interventions were randomised to care homes as follows: PCC + UE in 10 homes; PCE + UC in 10 homes; PCC + PCE in 10 homes and UC + UE continuing in 8 homes. All study interventions were funded by the study grant including: the cost of training and supervising PCC site staff; the cost of replacing the PCC-trained staff with relief staff during training and on-site facilitation; the cost of implementing recommended and agreed PCE interventions of approximately $10,000 per site.

Person-centred care. Kitwood’s (1997) PCC principles, using experiential and adult learning approaches, were facilitated by two chief investigators (Chenoweth and Stein-Parbury) with expertise in PCC approaches and one expert PCC trainer from Alzheimer’s Australia, employing a train-the-trainer processes. Five staff (one care manager, one Registered Nurse, two Enrolled Nurses or Assistants in Nursing, 1 Diversion/Recreation Therapist) from each of the 10 PCC + UE and 10 PCC + PCE homes were involved in the PCC training. The 32-hour off-site training occurred over 1 week, complemented by a further 32 hours of on-site education and support to implement PCC in daily care practices and recreation activities. Prior experiences, case studies, role plays and simulations were utilised to develop awareness and insight of the relationship between care and the resident’s QOL. The PCC trainer guided and supported PCC-trained staff to employ PCC learning resources, mentoring and role modelling in educating all care and therapy staff in PCC. With the support of their managers and the PCC trainer, direct-care staff members were assisted to develop person-centred resident care and recreation activity plans, and to implement changes in care routines and procedures, with the focus on improving residents’ QOL and reducing BPSD. Ongoing telephone support continued for PCC-trained staff by the PCC trainer until posttest.

Centred dementia environment design. Two chief investigators (CIs) with expertise in Person-Centre Environment design (IF and RF) and a Master of Design research student took responsibility for implementing the PCE interventions at each of the 10 PCE + UC and 10 PCE + PCC sites. The Environment Audit Tool (EAT) (Fleming et al. 2001) was employed to evaluate the relationships between operations and space in terms of effectiveness and ideal resident care, and determining required environmental changes to meet PCE principles at the sites. Discussions of EAT findings were held with the home’s executive staff and managers to initially determine their understanding of the dysfunction generated for residents through the poor physical environment features identified. Planning then occurred with these senior staff to determine the best ways to undertake the most essential and inexpensive environmental changes required. Planned modifications to the environment were then undertaken in each of the 20 homes by a contracted building company. The environment interventions, agreed to by the managers and priced by the contractor, were as follows: (1) two facilities needed extensions of activity space made by covering balconies or areas that were previously open; (2) two facilities had changes made to internal walls that would allow better visual access to activity and bedroom spaces; (3) one facility was to be altered to provide access to a courtyard from a dining area needed for activity and group activities; (4) two facilities needed internal divisions with added partitions to reduce the overstimulation in larger group spaces; (5) two facilities had walls removed to make subsitting areas visible to residents passing in the corridor; (6) one facility had fire doors relocated to improve access to the garden and (7) the remaining facilities all had some variation of external paving, new sitting areas in gardens or covered spaces in a landscaped exterior. All these changes were considered to provide maximum benefit in achieving improved support for staff undertaking PCC-focused activities while engaging with residents.

Person-Centred Care and Environment
Both PCC and PCE, described above, were implemented in 10 of the homes at the same time (PCC + PCE).

Usual Care and Environment
UC practices and care environments were maintained in eight homes throughout the intervention to follow-up periods, and regular records were made by RAs of any reported changes in the homes’ structures, management
arrangements, staff education and resident and staff profiles. The PCECAT and the EAT are repeated at posttest and follow-up in all 38 homes by two independent RAs and additional questions are asked of care managers and senior staff to ascertain any changes occurring during the study that might have changed care practice and/or the care environment and how the environment was being used by staff and residents.

MEASUREMENT

RAs, blind to interventions and to treatment group, obtained all the data. Training of RAs in specific areas of data collection occurred in four unrelated care homes prior to the baseline data collection. Interrater reliability between RAs was assessed as high for screening the homes (0.96) and for study participant measures (0.86). The home screening measure (PCECAT) was administered in all 89 consented aged care homes by RAs 1 and 2 prior to selecting the 38 eligible study sites. Environment, resident and staff baseline and pretest outcomes measures were administered in the 38 selected study sites by RAs 3, 4, 5, 6 and 7 prior to randomisation of sites to study interventions. RAs 1, 3, 4, 5 and 7 will continue to collect environment, resident and staff outcome data at posttest and at follow-up.

Blinding and Measures Taken to Reduce Bias

RAs 1 and 7 collected data 1 week apart. RA 1 used the PCECAT (Burke et al. n.d.) to collect the care quality and care environment assessment data at pre- and posttest and at follow-up, while RA 7 collected the pre- and posttest and follow-up environment data with the EAT (Fleming et al. 2001). RAs 3, 4 and 5 were assigned the task of collecting all resident and staff baseline and outcome data and were blinded to site allocation. However, the nature of the interventions was such that site allocation could become increasingly apparent over time due to changes or stability of the site environment and/or care practices. Therefore, RAs 3, 4 and 5 were rotated between sites and intervention groups across the three assessment time points, such that RAs 3, 4 and 5 did not visit a single site twice. Given the nature of the interventions (both changes in environment and staff education/training), it was not possible to conceal allocation from residents or staff, or personnel administering the interventions. Evaluation of the success of blinding will be done for all RAs during and at the completion of the study. All CIs are blind to group allocation and the statisticians and the health economist will be blind to site allocation during data analyses.

(A) Site Screening Instrument: To Determine Eligible Sites

Care and environment quality. Through direct observation, chart audit and interviews with site managers, staff, residents and families.

The PCECAT (Burke et al. n.d.) was developed and validated by a PhD nursing student and the CIs. It was informed by the Australian residential aged care accreditation standards, the building quality for residential care services certification requirements and Kitwood’s (1997) PCC principles, and validated against the Quality Interactions Schedule (QUIS) (Dean et al. 1993), the EAT (Fleming et al. 2001) and the Stirling Environment Assessment Tool (SEAT) (University of Stirling 2008). The 77-item PCECAT was used to screen all 89 consented sites to determine their potential for improvement with the PCC and PCE interventions in relation to both care quality and environment quality, with responses ranging from 0 (absent) to 3 (fully present). According to these criteria, 38 sites were allocated medium-to-low PCECAT scores and were thus considered by the study statisticians to be eligible for inclusion. None of these homes was considered to be providing sufficient levels of PCC and none had adequate PCC environments. Data were collected separately by RAs 1 and 2 and care managers trained in PCECAT assessment over an 8-hour period in all 89 care homes. RAs’ and managers’ scores were compared, and the RAs and study statisticians determined each home’s suitability for inclusion based on their potential for improvement in care and environment quality.

(B) Covariates: Potential Confounders Measured at Pretest

Resident demographics and clinical information. Derived from clinical charts and the person’s proxy, these were age, gender, ethnicity, English-speaking skills, previous occupation, marital status, number of living children, length of stay in high-care home, frequency of visits from family and friends, psychiatric history, tobacco, alcohol and drug history, dementia diagnosis and date, other diagnoses/comorbidities and all prescribed medications.

Global deterioration rating scale for assessment of primary degenerative dementia (GDS). (Reisberg et al. 1982). GDS validated measure of seven stages of clinically distinguished descriptions related to dementia, ranging from normal cognition to very severe dementia.

Care staff demographic questions. These were age, gender, ethnicity, English language skills, staff category, employment status, qualifications, experience and education levels in aged care and dementia care.
### TABLE 1
Summaries of key outcome measures

<table>
<thead>
<tr>
<th>INSTRUMENT</th>
<th>MEASURES</th>
<th>DOMAINS</th>
<th>OBTAINED BY</th>
<th>VALIDITY AND RELIABILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dementia quality of life (DEMQOL) (Smith et al. 2005)</td>
<td>QOL of people with dementia</td>
<td>Five domains including daily activities and self-care, health and well-being, cognitive functioning, social relationships and self-concept, filled out by both the person with dementia if possible and their proxy</td>
<td>Resident self-report if possible and resident proxy, either frequently visiting family/friend, or staff regularly caring for resident</td>
<td>Both patient and proxy forms have excellent internal consistency with Cronbach’s alpha of 0.87 or more. Test/retest reliability is good; patient version ICC’s is 0.84 when whole sample considered and 0.76 when only mild to moderate considered; proxy version ICC’s is 0.75, 0.67 and 0.84 for whole, mild to moderate and severe sample, respectively</td>
</tr>
<tr>
<td>Cohen-Mansfield agitation inventory (CMAI)-long form (Cohen-Mansfield 1999)</td>
<td>Agitation unique aspects of behaviour and the effects of cognitive enhancers and other types of psychotropic drugs on behaviour</td>
<td>Seven-point rating scale (1-never observed to 7-observed a few times in an hour) assessing the frequency with which patients manifest up to 29 behaviours associated with agitation, as observed by care staff over the past week</td>
<td>Review of clinical files, resident observation and consensus by staff who care daily for resident. RAs will refer to care staff who have daily and the closest contact with the resident to confirm assessment</td>
<td>Interrater reliability coefficients are high (0.88 to 0.93). Test/retest reliability is good (r = 0.74 to 0.92)</td>
</tr>
<tr>
<td>Emotional responses in care assessment (ERiC) (Fleming 2005)</td>
<td>The person with dementia’s emotional responses to care delivery</td>
<td>Observed emotional responses to care delivery quantifies the proportion of time, 3 positive and/or 3 negative emotional responses are made in defined situations</td>
<td>Direct observation of residents by RAs during care delivery</td>
<td>Interrater reliability (ICC) between experienced and novice raters for 6 subscales range from 0.81 to 0.89</td>
</tr>
</tbody>
</table>

### (C) Outcome Measures
Resident QOL and BPSD are the main outcomes assessed at pre- and posttest and at 6 months follow-up. Table 1 gives summaries of the outcome measures selected. Other outcome measures include: restraint rates, resident incident/accident rates and associated costs based on a review of accreditation and quality audit documents and records of accidents/incidents related to behavioural disturbance such as agitation, pacing and aggression.

Several primary outcome measures were nominated for the following reasons. The objectives of this trial are to improve QOL and QOC and obtain strong evidence to support PCC and PCE. In a recent related cluster RCT of PCC (Chenoweth et al. 2009), we used the Quality of Life in Late Stage Dementia (QUALID) (Weiner et al. 2000) to measure QOL, but found it was not responsive to the effect of PCC, in contrast to the widely used Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield 1999). The QUALID...
(Weiner et al. 2000) includes items on behaviour such as enjoyment of eating, touching and interacting, which are more subtle experiences and therefore more difficult to observe and judge than the overtly agitated behaviours recorded in the CMAI (Cohen-Mansfield 1999). Agitation is a major dementia-compromised behaviour, which is distressing for people with dementia and those in contact with them, and therefore an important factor in expressions of QOL. The DEMQOL (Smith et al. 2005) is a newer QOL instrument, and while validation studies appear promising, it has not yet been shown to be sensitive to the effects of interventions. We have therefore included the DEMQOL (Smith et al. 2005) and CMAI (Cohen-Mansfield 1999) as dual primary outcome measures related to QOL.

(D) Process Evaluation
Process evaluation includes assessment of care staff dementia knowledge, attitudes to people with dementia and QOC practice and care environment over time, and the PCC Champions’ knowledge, attitudes and care practices before and after the training program (Table 2).

(E) Economic Data
An economic assessment of the study interventions and their effects will be undertaken to identify, measure and value the relevant costs and consequences of interventions. This will take the form of an incremental analysis of the costs and consequences of the alternative interventions; comparing additional costs generated by PCC, PCE and combined PCC + PCE over that of UC and UE with the additional effects generated by the interventions in terms of QOL (DEMQOL), levels of agitation (CMAI), rates of restraint used and quality of interaction (QUIS). Quantities of resource use will be measured and unit costs or prices will be assigned, including cost of PCC training and implementation, and PCE assessment and intervention, using commercial rates and staff replacement using agency rates. The range of resources used in the ongoing implementation of PCC will be observed in a sample of the PCC sites to assess the extent to which this varies. Environmental modifications resulting from the PCE assessment will be recorded and market prices charged by tradespeople and for equipment will represent the costs of these aspects of the interventions.

Study Schedule
The 3-year PerCEN study commenced with screening of 89 potential care homes with the PCECAT between September and December 2008, with site selection confirmed by the EAT in January 2009. Pretest data collection commenced in 38 eligible homes in February 2009. The PCC + UE, PCE + UC and PCE + PCC interventions were implemented on site by the PCC trainer and/or the PCE experts for 4 months in a stepwise schedule in 30 homes, 1 to 4 months after pretest data were collected by RAs 1, 3, 4, 5 and 7 for all homes. Posttest data were collected by these RAs 4 to 8 months after the facilitated interventions were completed. Follow-up data will be collected 8 months after posttest in the same stepwise schedule commenced at pretest, due for completion in September 2011. This expanded timeframe will allow the study interventions to be in place for approximately 24 months before follow-up data are collected.

Data Analysis

Comparison of study completers versus noncompleters. Given the deteriorating nature of dementia, the comorbidities in residents and high staff turnover rates in residential aged care settings, a significant dropout is anticipated among residents and staff. For both types of participants, those who do not complete the study will be compared with those that do complete in terms of key baseline characteristics.

Scoring of outcome measures. Outcome measures will be scored according to the standard algorithm provided by each instrument’s developers. For the DEMQOL this will yield two scores, a resident self-report and a proxy report.

Missing data. A significant amount of missing data is anticipated, particularly in the resident self-report of DEMQOL, increasing with disease severity. Data from residents and time points with both self and proxy report will be used to estimate correlation and the size and direction of bias in proxy report relative to self-report. A comprehensive missing data analysis will be conducted to compare residents who do not complete the DEMQOL with those that do complete in terms of key baseline characteristics.

Analysis of primary outcomes. The study hypotheses about the effects of the interventions on the primary outcome measures will be tested with hierarchical linear models following the methods for analysis of nested cohort designs described by Murray (1998, pp. 184–190). The baseline outcome will be included as a covariate for the remaining two time points to maximise the precision of pairwise contrasts of treatment groups at post and follow-up assessments. The characteristics of site and residents considered to be potential confounders will be included as covariates. Following the methods described by Murray (1998, p. 137), covariates will be retained if: (1) there is evidence of confounding (estimates of treatment effect

Worldviews on Evidence-Based Nursing • Third Quarter 2011 161
### TABLE 2
Summaries of process evaluation measures

<table>
<thead>
<tr>
<th>INSTRUMENT</th>
<th>MEASURES</th>
<th>DOMAINS</th>
<th>OBTAINED BY</th>
<th>VALIDITY AND RELIABILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approaches to dementia questionnaire</td>
<td>Care staff process measure staff’s attitudes toward people with dementia</td>
<td>A 19-item scale: hope and recognition of personhood</td>
<td>self-completion by nurses, care and therapy staff and PCC champions</td>
<td>Two factors are internally consistent and stable ($r = 0.84$). There is good correlation between summed and factor scores for both of the ADQ factors</td>
</tr>
<tr>
<td>Quality of interactions schedule</td>
<td>Care staff process measures Quality of care interactions</td>
<td>Care activities and interactions are coded in one of five categories: positive social, positive care, neutral, negative protective, negative restrictive</td>
<td>Assessed by direct RA observation of resident and staff interactions and care practices in terms of the number and quality of care episodes and interactions occurring between residents and nurses, care and therapy staff during four 15-minute observation times each day over 2 days (6 hours per resident)</td>
<td>Observations and coding consistently produce kappa reliability statistics of above 0.75, with a range of 0.60 to 0.91</td>
</tr>
<tr>
<td>Environment audit tool</td>
<td>Care environment process measure The extent to which the environment has been changed in terms of relationships between operations and space in terms of effectiveness and ideal resident care that meet PCE principles</td>
<td>Reflects 10 key aspects of spaces correlated with expected impact on resident behaviour and provides an understanding of what spaces should be available to assist staff in caring for residents and incorporates the Alzheimer’s environment-behaviour factors model</td>
<td>Assessed by RA 2 through observation, focussed discussion with care manager and staff, and file audit</td>
<td>Common themes in responses</td>
</tr>
<tr>
<td>Focused interviews</td>
<td>Care managers’ reports of changes in the care home throughout the study period Care managers, nurses and care staff reports of impact of the interventions and the study on their behaviour Families of residents report on impact of interventions</td>
<td>Changes to structures, management procedures staff education and environmental changes Care practices, attitudes, learning, well-being, satisfaction with study procedures and outcomes for residents and staff Involvement in changes, resident assessment, planning and care, satisfaction with study procedures and outcomes for residents</td>
<td>Assessed by RA 1 through focussed discussions with care managers and staff Assessed by RA 3, 4 and 5 through focussed discussions with staff</td>
<td>Common themes in responses</td>
</tr>
</tbody>
</table>

---

162  Third Quarter 2011 • Worldviews on Evidence-Based Nursing
differ markedly adjusted vs. unadjusted models); (2) they explain significant variation in the outcome and (3) they improve the precision of the estimates of treatment effect. As the primary outcome measures yield continuous outcome variables, they will be analysed using SAS Proc Mixed, following the SAS code provided by Murray (1998, pp. 296–319).

The dose, duration and effect of the interventions employed will be evaluated at site and group level. Any unanticipated/unplanned care and environment changes occurring in any participating home will be noted in detail in researcher field notes and at posttest and follow-up manager/staff interviews, and accounted for when analysing all outcome data. The PCC interventions, dose and duration for individual participating residents will be evaluated by reference to their care and activity/lifestyle plans, and all outcome data. Where PCE interventions have an impact on individual participating residents’ personal spaces, particular resident PCE interventions, their dose, and duration will be evaluated by reference to the environment plans implemented and all outcome data.

Blinding of data collectors to intervention will also be accounted for. The RAs have been questioned on regular occasions about their awareness of the study interventions occurring and site allocation. To date, all RAs remain blind to study intervention, however, this checking procedure will continue until study end and potential or actual bias in data collection will be considered in analysis procedures.

**Analysis of secondary outcomes.** The study hypotheses about the effects of the interventions on the secondary outcome measures will be as for the primary outcome measures. For continuous outcome variables, hierarchical linear models will be estimated using SAS Proc Mixed, and for dichotomised variables, such as medication use, hierarchical logistic models will be estimated using SAS Proc Glimmix, following Murray’s code (1998, pp. 296–319).

**Qualitative responses include.** The impact of the intervention on nurse’s, care staff’s and site manager’s workload and work patterns; staff’s and managers’ perceptions of the study processes and outcomes; the Champions’ and staff’s perceptions of the enablers and barriers to implementing the PCC and PCE interventions; perceived successes of the PCC and PCE for care provision and resident outcomes, and perceived impact of the interventions on the organisation and family caregivers’ responses to a focused satisfaction interview, including their involvement in resident care planning, implementation and evaluation and perceptions of the care and environment quality. All qualitative data will be content analysed initially with the qualitative data analysis computer software, NVivo 8 (QSR International 1999). Three study team members with expertise in qualitative data analysis will independently employ an iterative analysis process to code and classify these data, then engage in reflection and discussion together to derive key themes for each question domain. Key themes will then be independently analysed by the three study team members for each of the participant group responses for the purposes of clarifying, confirming and extending the findings in relation to one another. These data will be confirmed and/or corrected by reference to key study participants, including family members. Consensus will be sought in interpreting and reporting thematic responses for key domains of inquiry. These data will assist when interpreting quantitative outcome data.

**Cost-effectiveness.** The results of the costs and outcomes will be presented separately (in a cost-consequence analysis) and in two cost-effectiveness ratios as a cost per unit change in the DEMQOL and cost per unit change in the CMAI. Economic analysis will calculate the incremental cost of providing PCE and PCC over usual environment and care. These results will be combined with the resident outcome results to determine incremental cost-effectiveness ratios. Uncertainty relating to the quantities and prices of the resources used in this study will be handled using sensitivity analysis. Because the major aim of the sensitivity analysis is to inform decision makers about the generalisability of the findings, we will undertake a scenario analysis as part of the sensitivity analysis. Such an analysis typically consists of base case (most typical), best case (most optimistic) and worst case (most pessimistic) scenarios.

**DISCUSSION**

The study protocol is of a novel randomised-group controlled trial evaluating the efficacy and cost-effectiveness of PCC, PCE and a combination of these two interventions for people living with dementia in the residential care setting. It is compared with usual dementia care (UC) and environment (UE).

The particular strengths of the PerCEN study design include being able to control for many of the confounding factors present in complex social and health research, so as to separate these from the independent variables being tested. Randomisation was employed to allocate treatments to eligible sites, matching for site characteristics to ensure balance of these across group allocation. When modelling the data, characteristics of site and residents that are considered to be potential confounders will be included as covariates. The aim is to achieve the most accurate and precise estimates of the treatment effect, so dose and duration of each of the interventions will be calculated.
at site and group level. The study was powered to detect a clinically meaningful difference, and sample size calculations were based on relevant estimates from a similar cluster RCT that this team has conducted (Chenoweth et al. 2009). The factorial design will allow us to estimate the separate and combined effects of PCC and PCE.

The disadvantage of the PerCEN study design is that we cannot blind the study participants to PCC and/or PCE, since all staff and many of the residents will become aware of the changes occurring in care practices through on-site PCC trainer support and/or to care environments though visible changes to physical indoor and outdoor spaces. It may also become apparent to RAs 1 and 7 that some changes are occurring in different homes as they collect the PCECAT and EAT data at each stage. However, it is unlikely that RAs 3, 4 and 5 will be aware of interventions occurring since they will not collect data from the same home at any stage. All RAs will be questioned on awareness of the study interventions and site allocation at each data collection stage to note potential and actual bias in data collection.

This is the first cluster-randomized controlled trial to specifically identify and specify the evidence-based theoretical personhood model derived by Kitwood (Kitwood & Bredin 1992), which has guided the development and evaluation of the PCC and PCE study interventions and measurement procedures.

To ensure the success of this complex intervention study, we carefully developed, described and tested both the PCC and the PCE interventions through a phased program of funded pilot studies and the CADRES RCT (Fleming et al. 2005; Chenoweth et al. 2009), with evaluation of previous implementations feeding back into the development of the PerCEN study interventions. The PerCEN study protocol should produce sufficient evidence for determining if PCC and/or PCE are worthwhile components of quality dementia care services, thereby assisting nurses and care managers in advancing quality nursing practice.

References


