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The Triple Challenge of Recruiting Older Adults With Dementia and High Medical Acuity in Skilled Nursing Facilities

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Abstract

Purpose—To describe strategies, culled from experience, for responding to several recruitment challenges in an ongoing randomized clinical trial of delirium in persons with dementia.

Organizing Construct—Delirium in people with dementia is common across all cultures. Little research supports the use of specific interventions for delirium. Recruitment of an adequate sample is critical to the validity of findings from intervention studies that form the foundation for evidence-based practice.

Methods—The trial referenced in this article tests the efficacy of cognitive stimulation for resolving delirium in people with dementia. Participants are recruited at the time of admission to one of eight community-based skilled nursing facilities (SNFs). Eligible participants are 65 years of age or older and community dwelling, and have a diagnosis of dementia and delirium. Recruitment challenges and strategies were identified during weekly team meetings over a 2-year period.

Findings—Recruitment challenges include factors in the external and internal environment and the participants and their families. Strategies that address these challenges include early site evaluation and strong communication approaches with staff, participants, and families.

Conclusions—The recruitment of an adequate sample of acutely ill older adults with dementia in SNFs can pose a challenge to investigators and threaten the validity of findings. Recruitment strategies that help improve the validity of future studies are described.

Clinical Relevance—Worldwide, over 100 million people will have dementia by 2050, placing them at increased risk for delirium. Recruitment strategies that improve the quality of nursing research and, by extension, the care and prevention of delirium in older adults with dementia during rehabilitation in SNFs are greatly needed.

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Keywords

Recruitment strategies; skilled nursing facilities; dementia

Older adults with dementia are at high risk for delirium, a state of increased confusion characterized by an acute and fluctuating decline in cognitive functioning (Inouye, 2006). The vast majority of people with dementia experience delirium during acute illnesses, and studies report that 24% to 76% die within 1 year of the index episode (Cole, McCusker, Dendukuri, & Han, 2003; McCusker, Cole, Dendukuri, Han, & Belzile, 2003). The World Health Organization estimates that there are over 35 million people worldwide who have dementia, and with the aging of the global population, this number will grow to more than 100 million by 2050 (World Health Organization & Alzheimer's Disease International, 2012). The greatest increase is expected among developing countries. Based on these projections, we can expect a worldwide increase in the number of people with delirium superimposed on dementia (DSD).

Delirium often persists long past the acute phase of an illness (Kiely et al., 2003) and results in an accelerated trajectory of cognitive and physical decline, prolonged rehabilitation, premature nursing home placement, and increased cost of care (Fong et al., 2009; Pitkala, Laurila, Strandberg, & Tilvis, 2005). Currently there are no strong evidence-based treatments for delirium. Professional organizations such as the European Delirium Association and the American Delirium Society advocate for research that will help resolve delirium during rehabilitation so that positive health outcomes are achieved (American Delirium Society, 2013; European Delirium Association, 2013).

Despite widespread skepticism, older adults with dementia can achieve positive functional outcomes and discharge destination following intensive inpatient or outpatient rehabilitation (Young, Xiong, & Pruzek, 2011; Yu, Evans, & Sullivan-Marx, 2005). There is little evidence, however, to guide recommendations for specific interventions that optimize outcomes for this vulnerable population (Muir & Yohannes, 2009). The post-acute care period is a critical transitional crossroad for people with DSD, and while the need for high-quality research that guides the care of these individuals is urgent, successful recruitment of individuals with both acute illness and neurological problems into clinical trials is known to be difficult (Newberry et al., 2010). Cognitive impairments due to delirium and dementia, the stress associated with illness and recent hospitalization, and the specter of permanent institutionalization make screening and enrollment into a research study overwhelming to many potential participants.

High-quality research depends on the recruitment of an adequate sample. There is little research on best strategies for recruiting in skilled nursing facilities (SNFs), long-term care settings where skilled nursing care, rehabilitative services, and other related health services are provided (Medicare, 2013). SNFs are settings where many older adults with DSD receive short-term rehabilitation services following hospitalization (Auster & Janda, 2009). Given the growing number of older adults with dementia who require rehabilitation, investigators need to understand and respond to recruitment challenges in order for their research to make a significant impact on long-term health outcomes, quality of life, and cost containment (Buntin, 2007).

Excellent articles on issues that affect the ability of investigators to recruit older adults with dementia in long-term care settings have been published (Mentes & Tripp-Reimer, 2002; Mody et al., 2008). We found no articles with a focus on the multiple challenges of recruiting older adults with DSD in SNFs, or research studies testing specific recruitment

techniques in this population. This article will begin to fill that gap by offering solutions to what we have experienced as a confluence of three major challenges in our current clinical trial: recruiting older adults with dementia who are experiencing high medical acuity in SNFs. We begin by briefly describing our clinical trial and then focus specifically on issues relevant to the external environment, the internal environment, and the research participants and their families that have the potential to affect recruitment in SNFs. Some of these issues are unique to the United States, while others are common to most healthcare systems.

Overview of Clinical Trial

Reserve For Delirium Superimposed on Dementia is an ongoing, 5-year National Institute of Nursing Research–funded study. The purpose of the study is to test the efficacy of cognitive stimulation for resolving delirium in persons with dementia subsequent to a hospitalization. The expectation is that resolution of delirium will help maximize the rehabilitation effort so these older adults regain adequate cognitive and physical function to return to their homes following the episode of acute illness. The protocol for the study received institutional review board approval and has been published (Kolanowski et al., 2011).

In this randomized repeated measures trial, participants are recruited and enrolled at the time of admission to one of eight SNFs located in central and northeast Pennsylvania. The sites were selected to be reflective of SNFs in the United States: they are community-based and include a mix of profit and nonprofit facilities. The project director (PD) contacts the admission coordinator at each SNF daily inquiring about new short-stay admissions. SNF staff has no role in recruitment, screening, or implementation of the intervention. The PD or other trained research staff screen new admissions for eligibility. Eligible participants are those who are 65 years of age or older, are community dwelling prior to admission, have a knowledgeable informant, and have both dementia and delirium. The diagnosis of dementia is based on a score of 3 or greater on the Modified Blessed Dementia Rating Scale (Blessed, Tomlinson, & Roth, 1968) and a Clinical Dementia Rating (Hughes, Berg, Danziger, Coben, & Martin, 1982) score ranging from 0.5 to 2.0, indicating mild to moderate stage dementia. The presence of delirium is established by screening potential participants using two instruments: (a) the Mini-Mental State Exam (Folstein, Folstein, & McHugh, 1975), a 30-item cognitive screen; and (b) the Confusion Assessment Method (Inouye et al., 1990), a standardized diagnostic algorithm for delirium. Additionally, all dementia and delirium diagnoses are adjudicated by a panel of three experts in dementia: a neuropsychologist, a neurologist, and a geriatrician. Exclusion criteria include having any neurological or neurosurgical disease associated with cognitive impairment other than dementia, including Parkinson’s disease with Lewy bodies, Huntington’s disease, normal pressure hydrocephalus, seizure disorder, subdural hematoma, head trauma, or known structural brain abnormalities; being nonverbal; having a life expectancy of 6 months or less; having acute major depression; and having severe hearing and vision impairment.

Following written consent, participants are randomly assigned to one of two conditions: cognitive stimulation (intervention) or usual care (control). Participants are assessed daily by trained research staff, blind to treatment condition, for delirium and physical and cognitive (attention, memory, orientation, and executive function) function for 30 days or until discharge. Participants in the intervention arm receive 30 minutes of daily cognitive stimulation delivered by trained research staff using simple recreational activities that are tailored to interests and ability. In addition to our primary outcomes, we collect satisfaction data from participants, their family members, and SNF staff.

The challenges we encountered in this trial were identified during weekly team meetings held over a 2-year period. The principal investigators (PIs), PD, and trained research staff

attend these meetings, where weekly subject accrual data are shared and discussed. These data include the number of potential subjects screened, the number of screen failures, and the reasons for failure. Actual versus expected enrollment is tracked over time so that patterns can be identified. Minutes of the meeting are taken and posted on a secured project website where all research staff can access the information. Because we systematically track enrollment, we are able to quickly identify problems with enrollment and discuss possible causes and potential solutions. For this article, we reviewed our weekly minutes and grouped our recruitment challenges into three broad conceptual areas: those related to the external environment, those related to the internal environment, and those related to the participants and their families. Potential strategies can be proposed by any team member and are considered successful when they result in increased participant accrual. The challenges and the strategies we found successful are described in the ensuing text.

Recruitment Issues Relevant to the External Environment

One of the earliest barriers to recruitment was a lower-than-expected rate of people with dementia being admitted for short-term rehabilitation in our SNF sites. Reasons for screen failures are listed in Table 1. Not having a dementia diagnosis was the second most common reason (~ 25%) for exclusion to date. While there has been a remarkable growth in the number of short-stay residents in the United States over the past decade, reports indicate that the proportion of those admitted to SNFs with a dementia diagnosis has actually decreased by 4.4% (Fullerton, McGuire, Feng, Mor, & Grabowski, 2009). Several factors may account for this somewhat counterintuitive finding. For one, increased support for community-based rehabilitation (home health and outpatient) may attract some individuals from institutional settings (Buntin, 2007). But as others have reported (Ferretti, Seematter-Bagnoud, Martin, & Bula, 2010), we also found that dementia diagnoses are under-reported in the medical record. There are also policies and regulations in the United States governing Medicare skilled care benefits that affect admission to SNFs. One of these is Medicare's "observational status" policy, which may disproportionally affect those with cognitive impairments.

Observational status (Feng, Wright, & Mor, 2012) is defined as short-term hospital care services (24–48 hr) that are delivered while a decision is being made about the most appropriate level of care for that patient. Increasingly, more U.S. patients' entire hospitalization is designated as observational status. In some cases this has been for up to 16 days. Unfortunately, if these individuals require rehabilitation care in an SNF, that care is not covered by Medicare Part A because time spent in observational status does not count toward the 3-day qualifying inpatient stay. This policy effectively reduces access to rehabilitation services for beneficiaries and is being legally challenged by the Center for Medicare Advocacy.

There are several strategies we use to address low enrollment, possibly linked to access issues and under-reporting of diagnoses in the target population. One of the most important strategies is careful selection of SNF sites. We strongly advise investigators to recruit SNFs that are in close proximity to several acute care facilities and to track the discharge patterns of these "feeder hospitals." These data can be obtained from the utilization review department at most acute care facilities. To maximize the pool of potential participants, investigators should be prepared to recruit a large number of SNFs to balance the monthly variation in acute care facilities' discharges to local SNFs. Care must be taken, however, to ensure that any differences in the characteristics of these multiple sites are accounted for in the study design. Using site as a covariate in analyses is one example of controlling for these differences.

We also suggest that investigators keep inclusion criteria as liberal as possible and minimize exclusions based on an acceptable benefit: risk ratio (Mody et al., 2008). This is critical to achieving a representative sample of adequate size. In consultation with our geriatrician, we relaxed our exclusion criteria for Parkinson's disease during the first year of the study after determining that it would not confound outcomes of the study. Investigators should track subject accrual data on a systematic and regular basis so that appropriate adjustments can be made if enrollment criteria become too restrictive.

Early in the trial we also learned that the number of admissions with cognitive impairments reported by SNFs was deceptively low because dementia diagnoses are often not noted in the medical record. For this reason we do not rely on the SNF staff or medical chart for screening purposes; rather, we use standard instruments to screen all potential participants for both cognitive impairments and delirium, the latter being notoriously under-recognized by healthcare providers (Fick, Hodo, Lawrence, & Inouye, 2007).

Recruitment Issues Relevant to the Internal Environment

Patient characteristics determine where rehabilitation care is delivered in the United States. Individuals with complex medical problems are generally cared for in inpatient rehabilitation facilities, while those with cognitive impairments go to SNFs (Buntin, 2007). SNFs have been described as unstable environments because of their high rate of staff and administrative turnover and the unpredictable external forces, such as regulatory changes, that influence how the facility operates (Buckwalter et al., 2009). Any of these factors have the potential to impact recruitment as well as the internal validity of a study.

High rates of staff turnover have an immediate impact on communication between the research staff and the SNF staff. To guard against communication problems, we use a number of strategies that work well in this environment. First, a best practice for recruiting in any research site is to engage the community and to learn about its culture and routine (Dubois et al., 2011). We do this by meeting with the administrative staff and identified gatekeepers well before the site becomes active. Because SNF patients receive many rehabilitation services (94% of our participants receive both physical and occupational therapy and 58% also receive speech therapy), we request a meeting with the heads of all these departments so we can coordinate schedules and the flow of participants through our study protocol. This is an important step in reducing the added burden that one more intervention may have on participants as well as the time pressure that all therapy departments experience in service delivery. We also meet with the direct care staff to explain the study and distribute flyers with a written explanation of the study and contact information for the PIs and PD.

We keep our research staff as stable as possible to balance the deleterious effects of high SNF staff turnover at the research sites. A high rate of SNF staff turnover means that these new staff may be unfamiliar with our research staff and processes. Stable research staff who are knowledgeable about the flow of work on the units, the culture of the site, and the project aims are in a good position to convey this information to new SNF staff in an engaging manner. We have found that retired nurses are an excellent pool of research staff who function exceptionally well in this environment. They understand the dynamics in institutional settings and can deal with staff issues and events that have the potential to affect the validity of the study, such as interruptions during study procedures. To maintain stability of research staff, we communicate frequently via email and phone and we host periodic social events for them. The PD is a key person who keeps in close daily contact with research staff in the field and promotes good working relationships among all members of the team.

As noted earlier, we do not involve SNF staff in recruitment, screening, or intervention implementation because of the time burden it imposes (Hanson, Gilliam & Lee, 2010). The PD initiates brief communication with SNF admission staff via phone or email on a daily basis in order to capture all potential participants. This is particularly necessary during surveyor visits, which come at unpredictable times. Like other investigators (Tilden, Thompson, Gajewski, Buescher, & Bott, 2013), we sometimes take a "time out" from recruitment during these periods because the survey takes precedence over other activities. We also keep staff involvement in assessments to a minimum, folding them into the unit workflow.

Incentives and tokens of appreciation for staff and administration are important in any study. While most of our contact is with the direct care staff, we find it important to incentivize all staff, including all therapy staff, because of their involvement in coordinating the participant's schedule for assessment and intervention (Mody et al, 2008). Failure to do so can lead to resentful demoralization of the therapy staff. For nursing and therapy staff we provide break snacks like coffee and donuts and we hold a $100 lottery every 6 months. To incentivize SNF administrators we offer free continuing education programs for their staff on common clinical problems that are unrelated to the study focus. We receive many requests for educational programs on the behavioral and psychological symptoms of dementia. Lastly, we publicize the SNF's involvement in our federally funded study in local newspapers and magazines (Tilden et al., 2013). Administrators appreciate the marketing value of these articles for attracting skilled care residents to their facilities. Skilled care residents bring greater reimbursement than long-term care residents.

Recruitment Issues Relevant to the Participants and Families

In Table 2 we list the demographic and baseline clinical characteristics of the sample we have recruited to date (N = 99). Our participants are acutely ill, mentally and physically impaired, and, based on their comorbidity scores, at high risk for rehospitalization (Charlson, Pompei, Ales, & MacKenzie, 1987). For these participants and their families, admission to the SNF is fraught with uncertainty about the eventual ability to return home. Periods of increased confusion due to the delirium heighten what is already a stressful situation. Understandably, family members may be reluctant to enroll their parent or spouse in a research study that involves assessments or treatments that might deplete what existing energy they have left (Newberry et. al., 2010).

We have employed several strategies that help address recruitment at the level of the participant and their family. It is not uncommon to find families in crisis upon admission to an SNF. Many older adults fear that this admission is the first step by the spouse or adult child in their plan toward permanent institutionalization. Anger and sadness are common reactions to admission. For many adult children, this is the first time they are confronting their parent's mental and physical frailties. It can be an emotionally draining experience as they try to sort out what may be causing the aberrant behaviors of delirium (lethargy, hyperactivity, agitation) they are witnessing. We have had several adult children speak about the lost time in resolving parent and child conflicts. We strongly recommend having a recruiter or screener with a mental health background make the initial contact with potential participants and families. Much of what needs to happen in that first contact is what Heggestad, Nortvedt, and Slettebø (2013) describe as "moral sensitivity" or attention to the values involved in a conflict-laden situation. A mental health background is invaluable for negotiating these situations.

Most of the responsible parties in our study are adult children (63.5%), and many live and work outside the area. Geographical distance complicates the recruitment process because

contact time may be prolonged. A recent retrospective analysis of six Alzheimer's disease cooperative study randomized clinical trials indicated that nonspouse caregivers are less likely to participate in dementia trials (Grill, Raman, Ernstrom, Aisen, & Karlawish, 2013). The investigators speculate that differences between adult children's and spouses' attitudes around burden and quality of life may explain these differences in research participation rates.

To address these issues we factor in extra time for the consent process (Mody et al., 2008), which in some cases may take as long as 72 hr when families are not local. We share the procedures we have in place to reduce burden and fatigue while highlighting the potential benefits of participating in the research (Marcantonio et al., 2008). Study benefits include a potentially helpful intervention and greater attention. Many older adults are motivated to participate in research by a desire to help others. We train research assistants to be sensitive to fatigue, to break down procedures into smaller units, and to return for daily assessments at a time when the participant is receptive to study procedures (Mody et al., 2008). Many of our outcome measures are obtained using observational instruments that do not require active engagement by the participant. We issue certificates of appreciation to all participants at discharge, and we track satisfaction by surveying participants, their family member, and the staff member assigned to the participant. To date, 76% of subjects and 69% of their families felt the intervention helped them recover. Over 86.2% of staff felt the intervention fit well into their care activities and participants' other therapies. These survey results are shared with potential participants and families during recruitment to illustrate what others have identified as positive benefits of the study.

Compounding recruitment issues are gaps in transition from the hospital to the SNF that threaten the ability of participants to function optimally (Toles, Abbott, Hirschman & Naylor, 2012). Missing or lost eyeglasses and hearing aids, for example, reduce participants' ability to become oriented to their new environment and greatly impede communication during screening and assessment. Because this happens frequently, we make a practice of always having hearing amplifiers and high-vision written materials available to facilitate communication during recruitment as well as throughout the study.

Conclusions

Global aging is fueling an urgent worldwide need for evidence-based interventions that support the recovery of older adults with DSD following acute illnesses. Investigators have the potential to make a significant impact on health care and cost by conducting quality research in SNFs where many persons with DSD receive rehabilitation services. There is very little research to support specific recruitment strategies for persons with DSD in SNFs; until these data are available, our experience with successful strategies may assist other investigators in the design of their recruitment plan. We found that investigators should be prepared to invest extra time and resources to maximize recruitment in SNF settings. This investment will help ensure an adequate sample, the validity of the study findings, and, ultimately, strong evidence for practice.

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Clinical Resources

- European Delirium Association: http://www.europeandeliriumassociation.com/
- American Delirium Society: http://www.americandeliriumsociety.org/
- Hartford Geriatric Nursing Initiative: http://consultgerirn.org/resources/hartford_geriatric_nursing_initiative_hgni/
- CONSORT Statement: http://www.consort-statement.org/consort-statement/overview0/
- Alzheimer's Association Research Center: http://www.alz.org/research/overview.asp

Table 1

Reasons for Screen Failures (N = 819)

Reason	*n*	%[a]
No consent to screen	233	28.4
No dementia	207	25.3
Exclusionary medical diagnosis	128	15.5
Responsible party not available	95	11.6
Vision or hearing impairment, nonverbal, non-English speaking	54	6.6
No delirium	40	4.9
Prior residence not community dwelling	21	2.6
> 72 hr from admission	13	1.6
Subject refused	8	1.0
Not hospitalized	3	0.4
Other	17	2.1

[a]Percentage of total screened.

Table 2

Demographic and Clinical Characteristics of the Sample (N = 99)

Variable	Mean ± *SD*/*n* (%)	Range	Possible range
Age (years)	83.40 ± 11.8	65–99	
Gender (female)	58 (58.6%)		
Race (White)	94 (95%)		
Marital status			
Married	38 (40%)		
Widowed	50 (52%)		
Divorced/separated	5 (5.2%)		
Single	3 (3.1%)		
Confusion assessment method	2.47 ± 0.8	0–4	0–4
Clinical Dementia Rating Scale	1.29 ± 0.5	0.5–2.0	0–3
Modified Blessed Dementia Rating Scale	6.40 ± 2.5	3.0–13.0	0–17
Mini-Mental State Examination	13.48 ± 6.3	0–28	0–30
Charlson Co-Morbidity Index[a]	1.66 ± 1.4	0–6	0–30

[a]Dementia diagnosis not included in score.