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Margaret J. Bull

Marquette University, margaret.bull@marquette.edu

Lesley Boaz

Marquette University, lesley.boaz@marquette.edu

Jennifer M. Sjostedt

Marquette University

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Margaret J. Bull

Marquette University College of Nursing, Milwaukee, WI

Lesley Boaz

Marquette University College of Nursing, Milwaukee, WI

Jennifer M. Sjostedt

Marquette University College of Nursing, Milwaukee, WI

Abstract

Recruiting older adults and their family caregivers into research studies presents challenges. Although the literature notes some general recruitment challenges, no studies specifically address the unique challenges of recruiting older adults who have Alzheimer's Disease (AD) and their family caregivers in studies about delirium or suggest using a framework to identify barriers to recruiting this population. In conducting a pilot study about preparing family caregivers to detect delirium symptoms in older adults with (AD) the researchers used the Public Health Model for identifying barriers to recruitment. The goals of this methodological article are to: (1) briefly describe the methodology of the pilot study to illustrate how the Public Health Model was applied in the context of the present study and (2) discuss the benefits of the Public Health Model for identifying the barriers to recruitment in a study that prepared family caregivers to detect delirium symptoms in older adults with AD. The Public Health Model helped us to identify four specific barriers to recruitment (lack of knowledge about delirium, desire to maintain normalcy, protective caregiving behaviors, and older adult's fears) and ways to overcome them. The Public Health Model might also help other researchers address similar issues.

The challenges of recruiting older adults, including those with Alzheimer's-type dementia (AD), into research studies are well-documented (Mackin et al., [2009](#); Miller, McKeever, & Coyte, [2003](#); Payne & Hendrix, [2010](#); Tsai et al., [2009](#)). Disease progression and "being too busy" have been noted as barriers to participation in some intervention studies (Heiney et al., [2010](#); Mackin et al., [2009](#); Tsai et al., [2009](#)). In addition, the stigma associated with dementia can heighten these challenges, a problem which can be unintentionally aggravated by the terminology used by researchers. In addition to terminology, researchers might be unaware of other factors that pose barriers to recruiting older adults with dementia and their family caregivers into research studies. This raises a question about the best way to identify barriers to older adults with AD and their family caregivers' participating in research. Researchers have not addressed this important topic in relation with recruiting participants in studies about delirium and few suggest using a framework to identify ways to overcome the barriers (Garand, Lingler, Conner, & Dew, [2009](#); Heiney et al., [2010](#); MacKenzie, [2006](#)). Using frameworks to guide research is a public health nursing priority and might serve as a best practice for identifying barriers to participant recruitment (Issel, Bekemeier, & Kneipp, [2012](#)). The Public Health Model provided a systematic approach for identifying barriers to participant recruitment in our study and can provide guidance to other researchers faced with similar challenges.

The goals of this methodological article are to: (1) briefly describe the methodology of the pilot study to illustrate how the Public Health Model was applied in the context of the present study and (2) discuss the benefits of the Public Health Model for identifying the barriers to participant recruitment in a study preparing family caregivers to detect symptoms of delirium in older adults with AD.

Pilot Study

Delirium superimposed on AD is common in older adults with prevalence ranging from 22% to 89% for these conditions occurring concurrently (Bellelli et al., [2007](#); Fick, Agostini, & Inouye, [2002](#); Voyer, Cole, McCusker, & Belzile, [2006](#)). Unlike AD in which mental status changes occur gradually, delirium is a life threatening, frequently reversible condition characterized by sudden onset and fluctuations in orientation, memory, disorganized thinking, perceptual disturbances, and compromised ability to communicate (Bond, [2009](#)). Delirium is frequently a symptom of an underlying illness or health problem that requires a medical evaluation. For instance, Rahkonen and colleagues ([2000](#)) found that delirium was the presenting symptom at time of hospital admission in 43% of older adults with infections, 25% with stroke, 18% with cardiovascular disorders, and 12% with drug related reactions.

Early recognition of delirium symptoms is critical to prevent the adverse outcomes for older adults. Delirium increases the older adult's risk of falls, and leads to a cascade of functional decline, lengthy hospital stays, and institutionalization (Fong et al., [2009](#); González et al., [2009](#); Rudolph et al., [2010](#); Witlox et al., [2010](#)). Delirium is also costly for the US health care system with estimates of annual costs ranging from \$38 to \$152 billion (Leslie, Marcantonio, Zhang, Leo-Summers, & Inouye, [2008](#)). Family caregivers can be vital partners in early recognition of delirium symptoms. However, family caregivers often attribute symptoms of delirium to aging or the progression of the AD (Bull, [2011](#); Fick, Hodo, Lawrence, & Inouye, [2007](#); Mittal et al., [2011](#); Wang & Mentis, [2009](#)).

The goal of our pilot intervention was to prepare family caregivers to detect symptoms of delirium in older adults with AD, and thus empower family caregivers to recognize delirium symptoms early, obtain a medical evaluation of the symptoms, and ultimately prevent the cascade of functional decline, morbidity, and mortality that might result if a medical evaluation of the delirium symptoms was not obtained. The specific objective of the pilot study was to determine the feasibility of the intervention to prepare family caregivers to detect symptoms of delirium in community dwelling older adults with early and mid-stage AD using a pre-post experimental design. Recruitment began after obtaining approval from the University's Institutional Review Board for the Protection of Human Subjects in Research. As part of the pilot study older adults were screened for symptoms of delirium before the family caregiver began the 4 week, telephone based intervention. Older adults with AD were asked to give assent for this initial screening and for a repeat screening when the family caregiver had completed two of the intervention modules. The educational intervention was delivered in weekly telephone conversations with the family caregiver; the length of the telephone conversation ranged from 30 to 45 min. As part of the intervention, family caregivers received a Resource Book with information on delirium and vignettes that illustrated symptoms of delirium and vignettes that illustrated only dementia symptoms. The Resource Book was used in conjunction with the telephone conversations. After the family caregiver completed two modules, arrangements were made for a home visit in which the interventionist and the family caregiver both screened the older adult for symptoms of delirium. The purpose of this home visit was to validate the family caregiver's assessment for symptoms of delirium in the older adult. Data were collected from family caregivers before beginning the intervention and approximately 7–10 days following completion of the intervention.

Participants were recruited through AD caregiver support groups and flyers distributed at an annual Walk to End Alzheimer's Disease sponsored by the local chapter of the Alzheimer's Association. Eight of 14 family caregiver/older adult dyads met the inclusion criteria and agreed to participate in the study.

Ethnicity of family caregivers who agreed to participate was White ($n = 5$), Black/African American ($n = 2$), and Hispanic/Latino ($n = 1$). Two older adults were ineligible, one family caregiver was having surgery, and three family caregivers indicated that the older adults did not want to talk with a member of the research team. One family caregiver stated that she thought the study might upset her mother.

Six of the eight family caregivers completed the intervention and the pre-post intervention data collection. These family caregivers stated that the intervention provided information that was needed by all family caregivers and noted that the telephone-based delivery of the intervention was convenient. Two of the family caregivers dropped out of the study. One family caregiver completed three of the four intervention modules but dropped out when the demands of providing care for both her mother and father escalated. The other family caregiver dropped out of the study after the second module as her father asked her if she was trying to “get rid of him” by participating in the study. By dropping out of the study, the family caregiver eliminated the interventionist's home visit to screen her father for symptoms of delirium and reduced her father's concern about the study leading to nursing home placement.

Application of the Public Health Model

The basic principles of the Public Health Model were used to guide the planning and evaluation for this clinical research project because the model emphasizes prevention and heightens a population or group's awareness of a public health problem (Issel, [2004](#)). As noted previously, using models to guide research and practice is a priority for public health nursing (Issel et al., [2012](#)). Often the target population for public health interventions is unaware of the health problem and risk factors, and consequently unlikely to define it as a problem. Unlike the Participatory Action Research Model in which the target population defines the health problem (Chenail, St. George, Wulff, & Cooper, [2012](#)), the researcher using the Public Health Model identifies the health problem requiring preventive interventions based on existing data about its severity, and factors contributing to its incidence or prevalence in the population or subgroup. The key principles in the Public Health Model are identifying the problem, identifying risk and protective factors, and developing, implementing and evaluating interventions (World Health Organization, [2012a,b](#)). Figure 1 illustrates the application of these principles in identifying barriers to participant recruitment in our study.

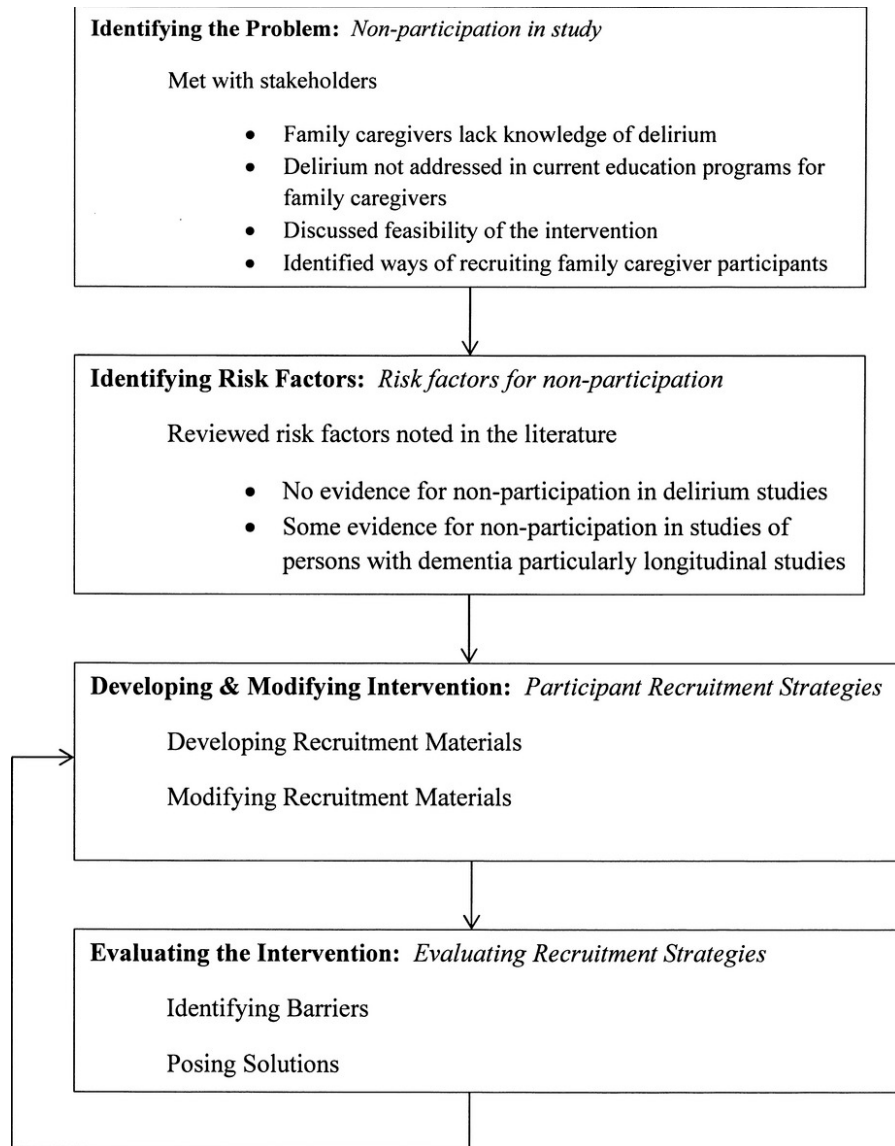


Figure 1. Principles of Public Health Models as Applied in our Study

Identifying the Problem- Nonparticipation and Delirium Awareness

The problem was twofold in that the target population of family caregivers was largely unaware of delirium and the morbidity and mortality associated with delirium. Secondly, this lack of knowledge about delirium was a factor contributing to nonparticipation in the study. Existing data in the literature indicated that delirium is a health problem among adults over 65 years of age and that older adults with AD are at higher risk for developing delirium than those who do not have AD (Michaud et al., [2007](#); Voyer et al., [2006](#)). Using the Public Health Model, the principal investigator (PI) identified and met with key stakeholders in the local chapter of the Alzheimer's Association to determine whether they viewed delirium as a problem for the population that they served, discussed the feasibility of the intervention, and discussed participant recruitment. The representatives of the local chapter of the Alzheimer's Association readily indicated that delirium and recognition of delirium were important in older adults with AD. The education programs that were offered by the Alzheimer's Association focused on dealing

with problem behaviors and the course of AD. While delirium was mentioned, content was not provided to help family caregivers recognize symptoms of delirium.

The CEO and Program Director for the local chapter of the Alzheimer's Association expressed support for the project and indicated that their organization connected with approximately 1,000 family caregivers for persons with AD in one metropolitan area geographically close to the university through outreach programs, support groups, and educational programs. They suggested that the Outreach Coordinators might facilitate participant recruitment through support groups for family caregivers. The terms AD and dementia were used routinely on the email announcements and flyers that that Alzheimer's Association sent to family caregivers about their programs so the research team did not hesitate to use these terms on the study recruitment materials.

Identifying Risk Factors for Nonparticipation

Review of the literature indicated that common risk factors for older adults' and their family caregivers' nonparticipation in research included “being too busy” to take time to participate in longitudinal studies, advanced illness in the older adult leading to frailty and increased vulnerability, and the stigma associated with the term dementia (Garand et al., [2009](#); Tsai et al., [2009](#); Mackin et al., [2009](#)). Older adults with advanced illness were excluded from our study thereby eliminating one risk factor. Considering that the intervention occurred over 4 weeks, the longitudinal impediment did not seem applicable. Other researchers reported success in using telephone based interventions (Bakas et al., [2009](#)) so the modality did not appear to be a factor contributing to nonparticipation. However, the terms *dementia* and *Alzheimer's disease* conjure up different mental images and meanings for each person faced with the disease, many of which convey negative images. A diagnosis or label of AD has been associated with stigma and negative stereotypes of the family caregiver and the older adult affected with AD (Graham et al., [2003](#); Liu, Hinton, Tran, Hinton, & Barker, [2008](#); Werner & Heinik, [2008](#)). Stigma associated with dementia also can result in isolation and social withdrawal of both the older adult with dementia and family caregiver (World Health Organization, [2012a](#)). Given that none of our potential subjects were newly diagnosed with dementia, one might expect that the older adults would have adjusted to the diagnosis. None of the articles specifically addressed risk factors for nonparticipation in research about delirium.

The family caregiving literature also provided some insights on potential risk factors for nonparticipation in research by suggesting that family members have a desire to protect the vulnerable older adult. For instance, Bowers' ([1987](#)) landmark study of family caregivers found that they often engaged in *protective caregiving* with the aim of protecting the older adult from “threats to self-image and assaults to personal dignity.” Dementia can negatively affect the older adult's self-image (Gardiner, Radian, Neiman, & Neiman, [2011](#)). It is possible that protective actions might include avoidance of situations that trigger agitation in the older adult. For example, Mahoney's study of vigilance ([2003](#)), found that family caregivers wanted to reduce exposure to triggers that might result in the older adult becoming upset or agitated. However, the literature does not specifically address family caregivers' protective actions related to nonparticipation in research.

Developing and Modifying the Intervention-Participant Recruitment Strategies

A one page brochure entitled *Preparing Family Caregivers to Detect Delirium in Elders with Alzheimer's Disease* described what was involved for the family caregiver and the older adult with AD. Support group facilitators were asked to share the brochure with family caregivers attending their sessions and ask those who were interested in more information about the study to give permission for the support group facilitator to send their names and contact details to the PI.

Given the positive response from the staff at the Alzheimer's Association, it was surprising that participant recruitment progressed at a slower than expected rate. In an effort to improve recruitment, the PI requested permission to present the study to family caregivers at the support group meetings. Attending these meetings provided insights about the reasons for the slow rate of participant recruitment, and issues that were important to family caregivers such as protecting the older adult with AD from situations that might be upsetting and keeping family life as normal as possible. At one of the support group meetings it became clear that the group facilitator viewed delirium as something that occurred only when AD was in the final stages and that nothing could be done about it. Given her perspective, she had not shared the brochure on the study with family caregivers who attended the support groups that she facilitated. The PI introduced the study to family caregivers attending this support group meeting and passed around a copy of the resource booklet titled, *Preparing Family Caregivers to Detect Delirium in Elders with Dementia*. One family caregiver commented that her spouse would not want to talk to us because her spouse felt that there was nothing wrong with him; he did not even acknowledge the diagnosis of AD. Also he did not think of his wife as a caregiver but viewed what she did as an extension of her spousal role. Another family caregiver noted that having a resource booklet laying around the house with the word dementia in the title could cause problems as her family worked toward maintaining life as close to normal as possible. The word dementia suggested a deviation from normal and emphasized that the spouse had AD. It is also possible that the word dementia might trigger problem behaviors in the person with AD, particularly if the older adult is in denial with respect to the diagnosis. Another family caregiver was enthused about the study and stated that she would talk with her mother about it. Although this family caregiver and her mother did decide to participate, the family caregiver noted that it was initially difficult to persuade her mother to agree to participate in the study. Her mother viewed the word delirium as meaning a person was "crazy." This mother kept telling her daughter that she was not crazy. The daughter indicated that it took some talking to get her mother to agree to being screened for symptoms of delirium as part of the study.

Listening to the audiotapes of the intervention also provided insights as to why family caregivers might choose to drop out of the study. For instance, one daughter told the interventionist that her father asked if she was participating in the study to try to "get rid of him." This family caregiver dropped out of the study after the second intervention module and would not make an appointment with the interventionist for the home visit to screen her father for symptoms of delirium. In retrospect, this daughter might have dropped out of the study to alleviate her father's concern that she was trying to place him in a nursing home.

In talking with other family caregivers about the study, it became apparent that they tended to confuse the terms delirium and dementia. One family caregiver was very enthused about participating in the study and reported that she had considerable experience with delirium as her mother had had it for

more than 15 years and had progressed to the point where she was no longer verbal. In talking with this family caregiver it became clear that she was talking about dementia and thought delirium was the same thing. Other family caregivers, who met the study criteria for inclusion, indicated that they had not heard of delirium and were only familiar with AD. Since most family caregivers were unfamiliar with the term delirium, we found that we needed to provide more detailed information on what delirium is and why it is a problem for older adults with AD and their family caregivers. Ways of heightening awareness of the public health problem through recruitment materials without actively delivering pieces of the intervention called for careful deliberation on best terminology to use and the amount of information to provide about delirium. Other investigators who are addressing public health issues that are not widely recognized by the target population might encounter similar challenges.

Evaluating the Intervention-Recruitment Strategies

Our initial recruitment strategies were not successful despite our efforts to obtain input from stakeholders who provided services to family caregivers. Table 1 summarizes the key barriers we encountered in recruiting participants and potential solutions. Lack of awareness about delirium, what it is and that it is distinct from dementia was a major barrier to recruitment. Providing limited information about delirium and that it is distinct from dementia is important. Describing delirium as a type of confusion that some older people have that is different from dementia conveys limited information without going into details included in the intervention modules.

Table 1. Recruitment and Retention Challenges and Potential Solutions

Barriers	Challenge for recruitment/retention	Potential solution(s)
Lack of knowledge about delirium	<ul style="list-style-type: none"> • Lack of awareness of delirium as distinct from dementia • Not aware of importance or associated morbidity/mortality 	Knowledgeable recruiter presents enough information to delineate what delirium is without delivering component of intervention
Maintaining normalcy	<ul style="list-style-type: none"> • Diagnostic label implies abnormality 	Avoid using medical diagnosis on intervention materials/resources that the older adult sees
Protective caregiving	<ul style="list-style-type: none"> • Threats to older adult self-image in screening for delirium • Avoiding situations that cause upset or agitation 	Provide examples of types of questions that will be asked of older adult Discuss with family caregiver types of situations that caused upset or agitation in the past
Older adults concerns or fears	<ul style="list-style-type: none"> • Potential fear/concern about institutional placement • Potential fear of meeting new person/stranger from study team 	Reassurance that educating family caregiver might help keep the older adult at home Discuss with family caregiver how new people have been introduced successfully in the past; having trusted family member present

We found that it is important to obtain input directly from the target population because family caregivers' expressed concerns about protecting the older adults from threats to self-image, and exposure to upsetting situations. Providing examples of the types of questions that the older adult will be asked might alleviate family caregivers concerns. Also eliciting information from family caregivers on the types of situations that have upset the older adult in the past might help to determine whether participation in the study would provoke upset or agitation. In an effort to maintain normalcy some family caregivers might completely avoid use of the terms AD (and dementia) and delirium and find alternative words more acceptable. Asking family caregivers if they discuss the older adult's diagnosis at home and if so, what words they use, can help investigators identify acceptable terms. Instead of using the term delirium investigators might substitute sudden confusion, sudden changes in thinking, or sudden mental fuzziness. Dementia or AD might be referred to as chronic or ongoing changes in memory or as one older adult stated, "I have forgetfulness." In some situations, it might be helpful to avoid using the terms dementia and AD entirely. For instance, when we revised the title of our resource booklet, we dropped dementia from the title.

It is vital to recognize concerns or fears that cognitively impaired older adults might have about meeting new people or possible institutionalization. It might also be important to discuss with family caregivers how new people have been introduced to the older adult in the past. Arranging to have a trusted family member or friend present to introduce the member of the research team, who is collecting data, might reduce fears. Also reassuring older adults that providing education to their family caregiver might help them to continue to provide care at home might allay fears about nursing home placement.

Insights to facilitate recruitment might be obtained from a pilot study, such as the one we conducted. However, it might be more efficient and equally effective to obtain input via an online support group for family caregivers. Investigators might join a group, introduce themselves, and request suggestions from family caregivers. Investigators might also conduct focus groups with family caregivers as a way of eliciting preferred terms and heightening their awareness of a problem, such as delirium.

The Public Health Model was beneficial for identifying (a) barriers to participant recruitment, (b) all of the stakeholders, and (c) stakeholders' perspectives and input. These steps are vital to successful recruitment of study participants. Using the Public Health Model as a framework also was beneficial in alerting us to family caregivers' misconceptions about delirium and obtaining specific information on the barriers to participant recruitment.

Although existing data play a key role in identifying the problem, it is also vital to identify all the stakeholders, both providers and members of the target group, because their input is critical in developing a successful recruitment plan and selecting appropriate terminology. Reports of other researchers' experience is helpful in anticipating methodological issues, however, a model provides a framework for obtaining information that provides more depth on the nature of the problem and insights on ways to address problems specific to a particular study. Specifically an awareness of the protective action of family caregivers provided insights on how to revise terms used on our study materials. Considering the stigma associated with the term AD, family caregivers of older adults with AD might refuse to participate in research that would place emphasis on the older adult's diagnosis. Researchers might consider this protective aspect of caregiving when preparing recruitment materials. Building trust with the older adult with AD and the family caregiver is essential in recruiting dyads. Conveying to older adults that an intervention might help the family caregiver to continue to care for

them at home can be critical in retaining participants and allaying older adults' fears that a study might result in nursing home placement.

In studies that involve recruitment of older adult/family caregiver dyads, it is essential to address concerns of both the older adult and family caregivers. The Public Health Model was helpful in identifying potential concerns of family caregivers and the older adults with AD. Other investigators also might find the Public Health Model useful in guiding their research and specifically in identifying barriers to recruitment and strategies to overcome them. The concepts in the Public Health Model are broad, making it easy to apply to various types of health problems and research situations.

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