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# Recruiting Community-Based Dementia Patients and Caregivers in a Nonpharmacologic Randomized Trial: What Works and How Much Does It Cost?

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## Abstract

**Objectives—**The aim of this study was to evaluate the yield and cost of three recruitment strategies—direct mail, newspaper advertisements, and community outreach—for identifying and enrolling dementia caregivers into a randomized trial testing a nonpharmacologic approach to enhancing quality of life of patients and caregivers (dyads).

**Method—**Enrollment occurred between 2006 and 2008. The number of recruitment inquiries, number and race of enrollees, and costs for each recruitment strategy were recorded.

**Results—**Of 284 inquiries, 237 (83%) dyads enrolled. Total cost for recruitment across methodologies was US$154 per dyad. Direct mailings resulted in the most enrollees ($n = 135$, 57%) and was the least costly method (US$63 per dyad) compared with newspaper ads (US$224 per dyad) and community outreach (US$350 per dyad). Although enrollees were predominately White, mailings yielded the highest number of non-Whites ($n = 37$).

**Discussion—**Direct mailings was the most effective and least costly method for enrolling dyads in a nonpharmacologic dementia trial.

### Keywords

caregiving; dementia care; home care; clinical trials

An estimated 36 million individuals worldwide suffer from Alzheimer's disease and related dementias (ADRD), creating a critical global public health concern and an impending epidemic (Alzheimer's Disease International & World Health Organization, 2012). As a cure is not in sight, research is essential that develops and tests effective treatments, whether pharmacologic or nonpharmacologic, for managing the disease. Most individuals with

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dementia and their family caregivers (dyads) live at home, and their recruitment into clinical trials is crucial to the success of the research process. Failure to enroll representative samples of adequate size threatens the generalizability and statistical power of randomized trials (Mody et al., 2008; Stahl & Vasquez, 2004; Tarlow & Mahoney, 2000). Recruitment of dyads into ADRD trials is difficult (Snyder, Papp, Bartkowiak, Jackson, & Doody, 2009), and insufficient participation can lead to clinical trials being abandoned (Mapstone, Elbourne, & Roberts, 2007). In addition, recruitment setbacks increase study costs and decrease efficiency (Hunninghake, Darby, & Probstfield, 1987). It is vital for researchers to identify and use effective recruitment strategies that are also not too costly (Mody et al., 2008).

Although barriers to participation in ADRD clinical trials are well documented (Bull, Boaz, & Sjostedt, 2013; Connell, Shaw, Holmes, & Foster, 2001; Murphy et al., 2007; Rabinowitz & Gallagher-Thompson, 2010; Schneider, 2012; Snyder et al., 2009), few studies examine the effectiveness and cost of different recruitment strategies (Buckwalter, 2009; Carr et al., 2010; Cole, Doan, Ballinger, & Brown, 2009; Dowling, Olson, Mish, Kaprakattu, & Gleason, 2012; Tarlow & Mahoney, 2000). Previous research provides recommendations for recruitment (Connell et al., 2001; Dowling & Wiener, 1997; Murphy et al., 2007; Nichols et al., 2004; Shatenstein, Kergoat, & Reid, 2008; Snyder et al., 2009) and enhancing ethnic/racial minority enrollment (Bachman et al., 2009; Gallagher-Thompson et al., 2006; Gallagher-Thompson, Solano, Coon, & Areán, 2003; Gelman, 2010; Hinton et al., 2010; Olin, Dagerman, Fox, Bowers, & Schneider, 2002; Rabinowitz & Gallagher-Thompson, 2010; Souder & Terry, 2009), but these are either for pharmacologic interventions (Carr et al., 2010; Schneider, 2012), or with few exceptions (Tarlow & Mahoney, 2000), have not compared the cost of methods for enrolling community-based dyads into nonpharmacologic dementia studies. Carlson et al. (2013), for example, described a culturally focused recruitment approach for a nonpharmacologic study; however, associated costs were not identified, and the target population was not community-dwelling dementia patients and their caregivers. The latter represents a significant research gap, given that most people with dementia in need of nonpharmacologic treatments live at home and these are promising approaches that can enhance quality of life for families (Ballard et al., 2009; Gauthier et al., 2010; Gitlin, Kales, & Lyketsos, 2012).

Involving families in trials of nonpharmacologic treatments remains a societal priority to advance comprehensive dementia care. This study examines the effectiveness and cost of three different recruitment strategies: direct mail, newspaper advertisements, and community outreach, utilized in a clinical trial, Project COPE (Care of Persons with Dementia in their Environments), that tested a nonpharmacologic intervention to improve daily function and quality of life of persons with dementia and their family members in a metropolitan area (Gitlin, Winter, Dennis, Hodgson, & Hauck, 2010).

## Method

### Sample

Individuals with dementia were eligible for study participation if they had a physician diagnosis of NINCDS/ADRDA (National Institute of Neurological and Communicative

Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association) criteria for probable dementia or Mini-Mental State Examination (MMSE) score <24, were ≥21 years, English speaking, needed help with daily activities or had behavioral symptoms, and lived with or within 5 miles of family caregivers. Caregivers were eligible for study participation if they provided ≥8 hr weekly oversight or care, planned to live in the area for 9 months, were not seeking nursing home placement, reported upset with managing patient care, were English speaking, and at least 21 years old. Dyads were excluded if either had terminal illness with life expectancy <9 months; had active treatments for cancer, >3 acute hospitalizations in past year; or involvement in another caregiver or dementia trial related to behavioral management. Individuals with dementia were excluded with schizophrenia or bi-polar disorder, dementia secondary to probable head trauma, or MMSE = 0 and bed-bound, as patients non-responsive to their environment would not benefit from the intervention.

## Recruitment

COPE evaluated a home-based nonpharmacologic program providing families specific skills and knowledge to enhance daily function and quality of life of individuals with ADRD (Gitlin et al., 2010). Over 4 months, families learned to monitor common health concerns (dehydration) and manage functional decline and behavioral symptoms through home visits from occupational therapists and an advanced practice nurse. As individuals with dementia were at mild to moderate disease stages, recruitment methods targeted family caregivers in a four-county metropolitan region between 2006 and 2008.

Three recruitment strategies: direct mail, newspaper advertisements, and community outreach, were used to enroll the targeted sample size of 237 dyads. The recruitment coordinator, a licensed social worker, implemented and managed recruitment activities. Activities included calling and emailing agencies serving ADRD families to introduce COPE and inquire about their willingness to prepare mailings describing the study, meeting with agency directors to discuss recruitment involvement, ordering newspaper advertisements, preparing mailings and presentations to agencies and health fairs.

Mailings to families by local aging services and previous study participants included an Institutional Review Board (IRB) –approved letter describing the study and inviting participation. Letters were printed on agency letterhead and signed by officials. The recruitment coordinator prepared mailings and attached the postage. Agencies addressed them, to preserve family confidentiality. Agencies were not paid for the time spent labeling envelopes. Letters were mailed to participants of adult day services (ADSs), family caregiver support programs (FCSPs), Alzheimer Association support groups, geriatric medical practices, home health care agency, paratransit, senior center, and previous study participants.

Media strategies included an IRB approved quarter-page display advertisement in local newspapers. Community outreach involved talks to regional aging organizations, informational booths at health fairs, and consumer-oriented conferences, and distributing study brochures to local public libraries and employees of the academic institution.

Caregivers contacting the research team were asked where they heard about the study, and their responses were recorded in a study log. Caregivers indicating word-of-mouth or who were unsure of recruitment source were considered as recruited from community outreach activity.

Recorded recruitment costs included research personnel time, materials (brochures, printing, stationary, postage), and newspaper advertisements. Personnel costs were calculated using the hourly rate (US$23/hr including fringe benefits) of the recruitment coordinator multiplied by time spent on recruitment. As relationships with some aging providers conducting mailings were established prior to the trial, time and associated costs for developing these relationships could not be determined.

For each recruitment strategy, three scores were derived: (a) total yield representing the percentage of caregiver inquiries resulting in study enrollment, (b) percentage of non-White enrollees generated, and (c) cost per dyad.

# Results

## Total Yield per Recruitment Method

Direct mailings produced the most inquiries and enrollees (Table 1). Twenty-six mailings, to an average of 100 households each, reached approximately 2,860 families. Of approximately 2,860 families receiving mailings, 158 individuals inquired about the study. Of these, 135 (85%) dyads were eligible and willing to participate and enrolled in the study. This recruitment strategy yielded 57% ($n$ = 135/237) of trial participants.

For advertisements, a total of 23 were placed in eight newspapers throughout a four-county region, resulting in 73 inquiries. Of these, 62 (85%) dyads were enrolled, representing 26% of the total sample ($n$ = 62/237). A lower yield was obtained from community outreach, which included nine presentations to regional aging organizations, attendance at seven health fairs and consumer-oriented conferences, and distributing study brochures to local public libraries and employees of the academic institution. This resulted in 53 inquiries from which 40 (75%) dyads were eligible and enrolled, representing 17% of total sample ($n$ = 40/237).

## Racial Composition

Despite the targeted region's racial diversity, only 29% of the total sample were non-White, most being African American (Table 1). Direct mailings yielded 37 non-White dyads (16%). In contrast, newspaper advertisements yielded 19 non-White dyads (8% of total sample). Community outreach resulted in the lowest yield; 12 non-White dyads enrolled (5% of total sample).

## Cost by Recruitment Method

Total cost for all recruitment strategies was US$36,440, representing an average cost of US $154 per enrolled dyad. Of total amount, direct mailing materials (brochures, printing, stationary, postage) and staff costs (115 hr) were US$5,901 and US$2,640, respectively, for a total cost of US$8,541, representing 23% of total recruitment expenditures. The cost was US$63 per dyad enrolled through direct mailing (Table 1).

The 23 newspaper advertisements were more costly at US$13,899. This represented 38% of total recruitment expenses, a cost of US$224 per dyad. Personnel cost for this activity was not calculated; time spent was nominal as advertisements were ordered via email or brief telephone calls.

Community outreach activities reflected the highest recruitment costs of US$14,000, representing 38.4% of total recruitment expenditures and a cost of US$350 per participant. The recruitment coordinator and another staff member (paid same hourly rate) provided nine presentations and attended seven health fairs. Each presentation and health fair was considered a 7-hr workday due to the travel involved. Therefore, personnel cost for these activities was calculated using the hourly rate (US$23/hr) multiplied by 7 hr for two staff members. The total time spent for presentations and health fairs was 16 days for a total personnel cost of US$5,152. In addition, the recruitment coordinator spent 167 hr calling and emailing agencies serving ADRD families to introduce COPE and inquire about their willingness to send mailings describing the study and meeting with agency directors per request to further discuss recruitment involvement for a total cost of US$3,848 (US$23/hr × 167 hr). Large numbers of brochures were distributed at presentations and health fairs due to the significant number of attendees. Brochure costs for these activities totaled US$5,000 (Table 1).

## Discussion

This descriptive, retrospective study provides preliminary insight into effectiveness and costs of three recruitment strategies in nonpharmacologic dementia trials: direct mail, newspaper advertisements, and community outreach.

Direct mailings to caregivers through community organizations, and particularly from ADS centers and the research center's registry, produced the most study inquiries by caregivers, resulting in the highest enrollment numbers, and was the least costly. Results suggest that families who self-identify as caregiving and are connected to a social organization respond to a call for study participation, in comparison with families who encounter study information from other sources such as media announcements. It also suggests that families connected to services and/or who participated previously in research may be more inclined to respond to an appeal for study enrollment.

A concern with this recruitment approach, however, is that families connected to social services may not represent the population at large without such access. It is unclear how families who respond to a direct mailing differ from families who do not or to families who are caring for persons with dementia but who do not self-identify as caregivers. As previous research suggests important differences between caregivers volunteering for a study and those who do not (Pruchno et al., 2008), more attention to sources of recruitment for trials is warranted.

In contrast, community outreach (presentations to aging providers, attending health fairs) generated the fewest enrollees and was the most costly. The poor yield demonstrates the inefficiency of this strategy. Nevertheless, potential hidden benefits were not captured.

Community outreach may enhance study visibility, provide venues for identifying agencies willing to conduct direct mailings, and build an inclusive relationship with the target population (Gelman, Faul, & Yankeelov, 2013).

The three recruitment approaches yielded a lower-than-desired enrollment of minority caregivers. Only 29% were non-White despite the racial diversity of the four-county region. This outcome is consistent with previous research, documenting minority underrepresentation in clinical trials (Areán, Alvidrez, Nery, Estes, & Linkins, 2003; Dilworth-Anderson & Williams, 2004; Gallagher-Thompson et al., 2003; Stahl & Vasquez, 2004; UyBico, Pavel, & Gross, 2007). Although staff attended six health fairs and presentations that targeted African American caregivers, no enrollees were generated from these events. Minority caregivers may be underrepresented in social service agencies. That the recruitment coordinator was not of the same cultural background may have created a barrier to recruitment (Gelman et al., 2013). It is also unclear whether low yield was due to underrepresentation or whether this group was less responsive to direct mailings. In addition, the mailings were not specifically tailored to minority populations, which may have hindered recruitment efforts (Lin, Lee, Modeste, & Johnson, 2012).

As the rate and cost of dementia among minority populations is disproportionately higher than among White older adults (Gaskin, LaVeist, & Richard, 2013), their inclusion in clinical trials is critical. Different methods for recruiting racial and ethnic minorities are needed to ensure their adequate representation in nonpharmacologic studies. Strategies may include outreach to community-based programs serving minority populations, partnership building with churches that have large communities as recruitment of care-givers requires access to large volumes of potential participants (Campbell et al., 2007) and designing culturally appropriate recruitment materials (Lin, Lee, Modeste, & Johnson, 2012).

The average cost to enroll a dyad was US$154 across recruitment methodologies. The least expensive was direct mailings (US$63), reflecting less than half of the average cost. Compared with direct mailings, newspaper advertisement costs were close to 4 times higher (US$224), and community outreach activities were more than 5 times as high (US$350) per enrolled participant.

Our analysis has several limitations. First, the research team had previously well-developed relationships with some providers conducting study mailings; consequently, associated costs to cultivate relationships could not be estimated. Significant resources may be required to establish and maintain community–academic partnerships, and future studies should examine such costs. Second, our study could not determine reasons participants responded to any one recruitment method versus the other, whether persons who responded to one approach would have also responded to another, or whether participants had exposure to more than one recruitment methodology. Nevertheless, findings that mailings were effective are consistent with other studies achieving successful enrollments by partnering with community organizations that work with families (Mendez-Luck et al., 2011).

In summary, the most effective and least expensive recruitment strategy proved to be mailings directed at family caregivers, primarily from mailings by ADS centers. Although the three strategies together yielded the needed sample size, future research should prospectively evaluate different recruitment strategies and family motivations for participating in nonpharmacologic clinical trials and responding to different recruitment strategies to advance cost-efficient approaches.

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## Biography

**Karen Morrison**, is a licensed social worker at Bayada Home Health Care in Philadelphia. She earned her master of social work from the University of Pennsylvania's School of Social Policy & Practice. Her work in varied health care, geriatric, and research settings has focused on interventions that enhance and support the independence, quality of life, and well-being of older adults living in the community. She has served as an interventionist and recruitment coordinator for various funded intervention studies including Project COPE, the focus of this study.

**Laraine Winter**, PhD, is a research psychologist at the Philadelphia VA Medical Center. Much of her prior research has focused on psychosocial interventions for families of persons with Alzheimer's disease and other dementias.Currently, she is engaged in research on traumatic brain injury in veterans and their families. Other research interests concern medical decision making concerning end of life care.

**Laura N. Gitlin**, PhD, is a professor in the Department of Community Public Health, School of Nursing with joint appointments in the Department of Psychiatry and Division of Geriatrics and Gerontology. She is also the director of the Center for Innovative Care in Aging at Johns Hopkins University. She is nationally and internationally recognized for her research on developing, testing, and implementing novel nonpharmacologic interventions to improve the quality of life of persons with dementia and their family caregivers and daily functioning in older adults with functional disability. She is a well-funded researcher, having received continuous research and training grants from federal agencies and private foundations for close to 28 years. A theme throughout her research is applying a social ecological perspective to health care and person-and family-directed approach as well as collaborating with community organizations and health professionals to maximize the relevance and impact of intervention strategies.

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## Table 1

Participant Yield and Cost per Recruitment Method.

| Recruitment method | Inquiries | Enrolled dyads | Percentage of enrollees (*n* = 237) | Enrolled dyads non-White | Percentage of enrollees (*n* = 237), non-White | Cost of personnel[a] (US$) | Cost of materials[b] (US$) | Total cost (US$) | Cost per dyad (US$) |
|---|---|---|---|---|---|---|---|---|---|
| Mailings (2,860 pieces) | 158 | 135 | 57 | 37 | 16 | 2,640 | 5,901 | 8,541 | 63 |
| Newspaper advertisements (23 total) | 73 | 62 | 26 | 19 | 08 | — | — | 13,899 | 224 |
| Community outreach activities | 53 | 40 | 17 | 12 | 05 | 9,000 | 5,000 | 14,000 | 350 |
| Total | 284 | 237 | — | 68 | 29 | 11,640 | 10,901 | 36,440 | 154 |

[a] Cost of personnel is the recruitment coordinator's hourly rate (US$23/hr) multiplied by the number of hours spent on each activity.

[b] Materials included brochures, printing, stationary, and postage.