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RESEARCH ARTICLE

Advancing family dementia caregiver interventions in low- and middle-income countries: A pilot cluster randomized controlled trial of Resources for Advancing Alzheimer's Caregiver Health in Vietnam (REACH VN)

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Abstract

Introduction: Low- and middle-income countries have rapidly increasing numbers of people with dementia, yet little evidence on family caregiving interventions. We tested the preliminary efficacy and feasibility of a family caregiving intervention in northern Vietnam.

Methods: Nine clusters comprising 60 family caregivers were randomized to a culturally adapted version of a four- to six-session, multicomponent intervention delivered in-home over 2 to 3 months, or enhanced control. Eligible caregivers were ≥ 18 years of age and scored ≥ 6 on the Zarit Burden Inventory (ZBI).

Results: Fifty-one caregivers (85%) completed the study. Using analysis of covariance with 3-month assessment as the outcome and baseline assessment as a covariate, intervention group caregivers had an average ZBI (primary outcome) score 1.2

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standard deviation (SD) lower ($P = .02$) and Patient Health Questionnaire-4 (psychological distress) score 0.7 SD lower ($P = .03$) than controls.

Discussion: In the first study of its kind in Vietnam, a culturally adapted, manualized, family caregiver intervention was both efficacious and feasible.

KEYWORDS

Alzheimer's disease, dementia, family caregiving, global health, low- and middle-income countries, non-pharmacological interventions, Vietnam

1 | INTRODUCTION

Although Vietnam and other low- and middle-income countries (LMICs) face an enormous public health challenge as their populations age and the numbers of older adults with Alzheimer's disease and Alzheimer's-related dementias (AD/ADRDs) increase,^{1,2} many are not well-prepared to provide effective care and support to family caregivers. Because AD/ADRDs are among the most disabling non-communicable diseases, family members are often called upon to provide the bulk of day-to-day care, particularly in LMICs where nursing homes and other types of formal support services are scarce.³ Little is known, however, about which caregiver interventions are most effective and sustainable in LMICs, creating a critical evidence gap and barrier for policymakers.⁴

Supporting family caregivers through community-based programs is widely viewed as an essential part of national plans to address AD/ADRDs.⁵ This is also true for Vietnam, a country where very substantial gaps in diagnosis, care, and services for persons with dementia and their families exist in the healthcare system and efforts are underway to develop a national plan to help address these issues.⁶ The reason is that these programs and services are essential to mitigate the adverse social, economic, and health/mental impacts of caregiving that are well-documented in the United States and other high-income countries (HICs).⁷ These adverse impacts disproportionately affect women who provide the bulk of family AD/ADRD caregiving. In LMICs, families may be particularly vulnerable to the negative economic impacts of caregiving because many lack economic resources and access to long-term services and supports.

We are learning much more about how best to support family dementia caregivers in HICs. There is now a broad consensus, for example, that the most effective caregiver interventions are multi-component and often include education, skill-building to manage difficult behavioral problems, stress reduction, and referral to community resources.^{7,8} There is a need to understand whether these interventions are also effective in LMICs, where the resources and supports for caregivers may be more limited.

This study presents the results of the first clinical trial to address this critical evidence gap in Vietnam, a country with one of the world's fastest growing elderly populations.⁹ We adapted and tested a version of REACH (Resources for Enhancing Alzheimer's Caregivers Health),^{10,11} one of the most widely tested models in the United States,

which has been found to be effective and feasible in multicultural populations in the United States¹²⁻¹⁵ and internationally including Hong Kong.¹⁶ The specific aims of this study were to examine the preliminary efficacy and feasibility of a culturally adapted version of REACH (ie, REACH Vietnam) for family members of persons living with dementia in Vietnam.

2 | METHODS

2.1 | Study design and participants

From June to October of 2018, we conducted a cluster randomized controlled trial (RCT) among family caregivers of persons with AD/ADRDs who were identified through a registry of individuals who had been diagnosed previously with dementia by neurologists from the Vietnam National Geriatric Hospital (NGH) in collaboration with local commune health stations. Details of the study can be found in the published protocol.¹⁷ The study was registered with clinicaltrials.gov (identifier NCT03587974). Informed verbal consent was obtained from all participants and the protocol was approved by the institutional review boards of University of California, Davis, University of South Carolina, and the Vietnam NGH. The study was designed primarily as a feasibility study that also provided an opportunity to estimate effect sizes and to examine preliminary efficacy.

Participants resided in designated clusters (ie, geographic area served by a local health station) in Soc Son, a semi-rural district in Hanoi with a longstanding history of collaboration with the NGH. Soc Son is more economically advantaged compared with many other semi-rural areas due to its proximity to Hanoi and location near the international airport, an area undergoing considerable economic development. A convenience sample of 12 clusters was chosen based on their proximity to NGH, their participation in the NGH dementia registry, and history of successfully participating in prior research projects and initiatives. After the start of the study, we added as a criterion a minimum of three persons recruited from each cluster. This latter criterion was added based on resource considerations and the difficulty of estimating important study parameters (eg, inter-correlation coefficients) with too few participants. A cluster design was chosen because of concerns about possible contamination effects if participants in the control and intervention condition resided in the same community.

NGH staff contacted families of elders with dementia, introduced the study, and screened the caregivers for eligibility criteria. Caregiver inclusion criteria included age 18 or older, family member most involved in the dementia patient's day-to-day care, a score on the Zarit Burden Interview (ZBI) (4-item) of ≥ 6 ,^{18,19} and caring for an older adult with a dementia diagnosis and a Clinical Dementia Rating (CDR) score of 1 or above.²⁰ We excluded caregivers identified as having difficulties in the consent process due to cognitive impairment or severe sensory impairment. Caregivers meeting inclusion criteria were asked for permission to have research staff contact them to set up an enrollment visit. During the enrollment visit, which took place several weeks after the initial screening, research staff provided additional information for the study, completed verbal consent, and collected baseline data. Participants were reimbursed the equivalent of US \$9 for their participation in each session.

As part of the consent process, all caregivers were informed that this was a voluntary study and that they could withdraw at any time.

2.2 | Randomization and masking

Randomization was at the level of clusters, defined as geographic areas (ie, communes) served by commune health stations which have a population range of ≈ 5000 -15,000 people. Randomization was conducted by one of the study investigators residing in the United States through the flip of a coin.

At the time of consent, participants were informed about their allocation to either the enhanced control or the intervention condition. Research assistants who conducted the 3-month outcome assessment were masked to allocation. Baseline assessments were conducted by research staff who were not masked to allocation.

2.3 | Procedures

Participants in the intervention group received REACH VN, a culturally adapted version of the REACH VA (Department of Veteran Affairs) intervention.¹² REACH VA is based on REACH II²¹ and consists of four "core" training sessions on problem solving, mood management/cognitive restructuring, stress management (eg, signal breath, pleasant event scheduling), and communication, plus up to two additional sessions based on caregiver's needs and clinical judgment.^{11,12,21} In REACH VA, the sessions last 1 hour and are delivered by a trained interventionist by telephone, telehealth, or face-to-face.

Interventionists were trained and certified by a senior member of the research team (HN) who is bilingual and was herself certified by the REACH VA intervention by the Memphis Caregiver Center affiliated with the University of Tennessee. Training of interventionists in Vietnam consisted of didactic sessions based on the REACH VA training materials as well as "hands-on" field experience in a case series prior to the study onset in which interventionists worked directly with HN.

Our culturally adapted and manualized intervention, REACH VN, is based on the REACH VA intervention, with modifications to make

RESEARCH IN CONTEXT

- 1. Systematic review:** As background to this study the authors conducted a scoping review of evidence for non-pharmacological interventions for family caregivers that had been conducted in low-, middle-, and high-income countries in Asia.⁴ Of 30 clinical trials identified by this search, only 4 were conducted in low- and middle-income countries and none in Vietnam (a low middle-income country). Although studies in high-income countries reported generally positive outcomes for caregivers, there was a striking gap in terms of evidence for low- and middle-income countries in Asia, which are projected to experience a rapid increase in the number of people living with dementia in coming decades.
- 2. Interpretation:** Our findings show that a culturally adapted and relatively brief family caregiver intervention was both efficacious and feasible in Vietnam. Caregivers who received the intervention showed significantly reduced caregiver burden (primary outcome) and reduced psychological distress (secondary outcome) but no significant improvement in knowledge about Alzheimer's disease (secondary outcome). Effect sizes were relatively large for both caregiver burden and psychological distress. Our findings are novel, representing the first test of a family caregiving intervention in Vietnam and one of the few among low- and middle-income countries in Asia.
- 3. Future directions:** Our results indicate the need for replication in a larger study under conditions that more closely resemble those in routine service delivery settings in Vietnam (eg, delivery of the intervention by local care providers and community outreach workers) to enhance sustainability at the local level and to guide policymakers as they seek models of support for caregivers that are promising for broader implementation and sustainability. Additional research is also needed to better understand the mechanisms that may explain the efficacy of this intervention and magnitude of the effect sizes among Vietnamese caregivers.

it suitable for the context of a semi-rural area in Vietnam. We used a multi-step cultural adaptation process guided by existing frameworks commonly used in global health.²² Although a full description of the adaptation process, modifications, and rationale is beyond the scope of this paper, the following is a summary of significant changes made to intervention content, context/delivery, and training.²³ Changes to content included numerous modifications of the intervention manual and caregiver notebook to make the scripts, examples, and resources appropriate to the culture and literacy level of the target population

(eg, substituting culturally relevant examples, simplifying language), and expanding the amount of time in across intervention sessions devoted to caregiver education about AD. Changes to context/delivery included participation of multiple family members in the intervention when appropriate, engaging the male head of the household in the initial session to facilitate participation and retention, and in most cases conducting weekly rather than biweekly sessions to sustain momentum. Changes to training included supplementing standard REACH VA training with principles of Buddhism to enhance interventionist skills and conducting a small case-series to give interventionists hands-on experience.²⁴

For this study, all interventionists were female healthcare and allied professionals including nurses, physicians, and social workers. Home visits were conducted by pairs of interventionists, one playing a lead role and the second a supportive role. Participants assigned to the enhanced control condition received a single face-to-face session at the time of enrollment in the caregiver's home (or another place of their choosing) that focused on education about the nature of dementia and included the provision of written educational materials. In addition, any safety issues identified during the single home visit were addressed by research staff.

2.4 | Study outcomes and their assessment

The objectives of this study were to assess both preliminary efficacy and feasibility of the intervention. For preliminary efficacy, the primary outcome was caregiver burden measured by the 4-item Zarit Burden Inventory (ZBI).¹⁸ Secondary outcomes were depression/anxiety symptoms measured by the Patient Health Questionnaire 4 (PHQ-4)²⁵ and Alzheimer's knowledge measured by the 30-item Alzheimer's Disease Knowledge Scale.²⁶ Primary and secondary outcomes were assessed at baseline and after completion of the intervention (\approx 3 months after enrollment). The feasibility outcomes were assessed in terms of cluster recruitment (% of clusters randomized that recruited minimum number of caregivers), individual recruitment (% of eligible caregivers who enrolled), retention (% of caregivers enrolled who completed study), intervention fidelity (% of sessions with delivery of all required activities based on standardized forms completed by interventionist), and assessments (% of participants with complete data). Baseline assessments were conducted at the time of enrollment by bachelor's level or higher research staff. Assessments at 3 months were conducted in the participants' homes by bachelor's level research staff masked to allocation.

2.5 | Statistical analyses

Characteristics of the caregivers and the care recipients were compared between the two groups using a two-sample *t* test or chi-square test; the Wilcoxon rank-sum test or Fisher exact test were used if needed due to violations of the underlying assumptions. Primary analysis of the intervention effect used an intent-to-treat approach, in

which groups were compared based on randomization assignment. To account for the clustering of participants by commune, mixed-effects models that included a cluster-specific random effect were used to estimate differences between groups. Models utilized the post-intervention assessment as the outcome and included the baseline assessment as a covariate. The post-intervention assessment was divided by the standard deviation (SD) in the entire sample at baseline, so that interpretation of model coefficients was in terms of standard deviation units. Model assumptions were checked and met by the data. All analyses were conducted in SAS, version 9.4, and a *P*-value $< .05$ was considered statistically significant.

2.6 | Data monitoring, safety, and quality control

The study had a safety officer (SO) but did not have a data safety monitoring board (DSMB). The rationale for not having a DSMB was that this was a single-site, minimal-risk clinical trial with a relatively small number of subjects in total. The lead investigators met with the SO during the clinical trial to review the progress of the study and adverse events.

3 | RESULTS

3.1 | Comparison of subject characteristics in intervention and enhanced control groups

The characteristics of the 51 participants who completed the study are shown in Table 1. In both groups, most caregivers were either daughters or daughters-in-law, and the mean years of formal education were <9 . Most of the care recipients were female with moderate-to-severe dementia based on the mean CDR scores of 2.6 and 2.5 in the enhanced control group and intervention group, respectively. There were no statistically significant differences in the characteristics at baseline except for the number of hours providing care to the person with dementia each week, which was significantly higher in the enhanced control condition compared with the intervention group ($P = .03$).

3.2 | Primary and second caregiver outcomes

There were no significant baseline differences between the two groups in primary or secondary outcomes, including the ZBI ($P = .9$), PHQ-4 ($P = .5$), and Alzheimer's knowledge ($P = .7$) (see Table 2). Using analysis of covariance (ANCOVA) to evaluate the intervention effect, with the 3-month assessment as the outcome and the baseline assessment as a covariate, we found that the REACH VN group had average ZBI scores 1.2 SD lower ($P = .02$) than the enhanced control group at 3 months. For the secondary outcomes, PHQ-4 scores for the REACH VN group were 0.7 SD ($P = .03$) lower than the enhanced control group at 3 months (see Figure 1). There was no significant difference in change in Alzheimer's knowledge scores (estimated difference = 0.2 SD lower in REACH VN compared to the enhanced control, $P = .7$, 95% confidence interval [CI]

TABLE 1 Pilot cluster RCT caregiver participant characteristics

	Enhanced control (n = 26)	REACH VN (n = 25)	P-value
Caregiver characteristics			
Age ^a	58.7 (13.9)	59.0 (10.4)	.9
Education (y) ^b	7.2 (2.6)	8.3 (3.4)	.2
Male (%)	19.2	8.0	.4
Marital status (%)			.4
Never married	0	0	
Married/living with partner	96.1	88.0	
Separated/divorced	3.8	8.0	
Widowed	0	4.0	
Other	0	0	
Relationship to care recipient (%)			.6
Son/son-in law	7.7	0	
Daughter/daughter-in-law	65.4	68.0	
Spouse	26.9	28.0	
Other	0	4.0	
Caregiving (y) ^c	9.5 (10.6)	7.0 (7.0)	.3
Daily caregiving (%) ^d			.03
< 1 h	0	0	
1-2 h	3.8	12.5	
3-4 h	3.8	25.0	
>4 h	92.3	62.5	
Care recipient characteristics			
Age	82.8 (11.1)	83.7 (11.6)	.8
Male (%)	23.1	24.0	1.0
CDR	2.6 (0.6)	2.5 (0.6)	.2

Abbreviations: CDR, Clinical Dementia Rating; RCT, randomized controlled trial; REACH VN, Resources for Advancing Alzheimer's Caregiver Health in Vietnam.

^aCaregiver age missing for two individuals.

^bCaregiver education missing for five individuals (three Enhanced Control, two REACH VN).

^cCaregiving (years) missing for three individuals (two Enhanced Control, one REACH VN).

^dDaily caregiving missing for one REACH VN.

TABLE 2 Analysis of primary and secondary outcomes

	Enhanced control (n = 26)	REACH VN (n = 25)	P-value*
Primary caregiver outcome			
ZBI (baseline)	6.8 (2.3)	6.7 (2.1)	.9
ZBI (3 mo)	5.5 (3.4)	2.9 (2.4)	.02
Secondary caregiver outcomes			
PHQ-4 (baseline)	4.6 (2.8)	4.1 (3.0)	.5
PHQ-4 (3 mo)	2.9 (2.8)	0.9 (1.0)	.03
AD Knowledge (baseline)	18.8 (2.1)	19.0 (2.2)	.7
AD Knowledge (3 mo)	20.1 (2.0)	19.9 (3.2)	.7

Abbreviations: AD Knowledge, Alzheimer's Disease Knowledge Scale; PHQ-4, Patient Health Questionnaire-4; REACH VN, Resources for Advancing Alzheimer's Caregiver Health in Vietnam; ZBI, Zarit Burden Inventory 4-item.

*P-value is from a model accounting for the clustering of individuals in the same community. Models for the 3-month outcomes included the baseline value as a covariate.

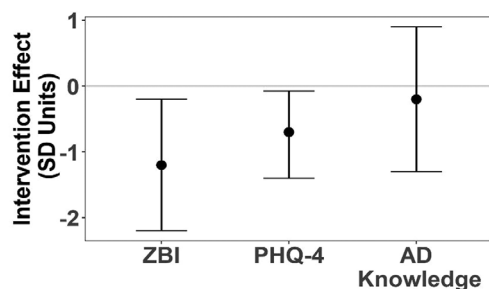


FIGURE 1 Effect size for primary and secondary caregiver outcomes in a cluster randomized controlled trial (RCT)

for difference: $-1.3, 0.9$). Secondary analyses also considered the addition of caregiver hours to the model, as this was significantly different between the groups, but there was no impact on the effect sizes (ZBI: 1.1 SD; PHQ-4: 0.7 SD). No adverse events occurred among study participants (ie, family caregivers).

3.3 | Feasibility outcomes

A total of 148 caregivers in 12 clusters were screened for eligibility (see Figure 2). Three (25%) of the 12 clusters (one randomized to the intervention and two to the enhanced control condition) were excluded due to low recruitment (fewer than three eligible caregivers identified). Of the 146 caregivers who were screened in the remaining nine clusters, 71 met study criteria, and 60 (85% of those caregivers who were eligible) were successfully randomized. Of the 71 eligible participants, 7 (10%) declined to participate and an additional 4 were excluded because the target of 60 caregivers had been reached. Of the 60 participants randomized (across nine clusters), 51 completed the study (26 in the control group and 25 in REACH VN intervention). Reasons for caregiver attrition included care recipient passing away ($n = 5$, two in intervention and three in control), caregiver decided not to participate ($n = 3$, due to lack of time and other reasons), and one caregiver was found to be ineligible due to significant cognitive impairment. Among the 25 caregivers who completed the intervention, 100% completed at least three sessions. Based on a review of standardized treatment delivery forms completed by the interventionists at the end of each session for the REACH VN groups, all required elements were completed for 98% of session 1, 96% for session 2, 92% for session 3, 87% for session 4, and 100% of final (closure) sessions. Baseline and 3-month assessments were successfully completed for all 51 participants who completed the study.

4 | DISCUSSION

To our knowledge this is the first study to test the efficacy of an AD/ADRD family caregiving intervention in Vietnam and one of the few conducted in an LMIC in Asia.⁴ The REACH VN intervention, a culturally adapted caregiver intervention, was both efficacious and feasible

when delivered to a community-based sample of caregivers in a semi-rural area outside of Hanoi, Vietnam.

For our primary outcome (caregiver burden), family caregivers who were in the intervention group had improved outcomes compared with those in the enhanced control group. Despite significant improvement in burden from baseline to 3 months in our enhanced control group, the effect size demonstrated in this study is considerably larger compared with effect sizes for REACH VA and other comparable interventions in the United States. The effect sizes for caregiver depression and anxiety symptoms, while not as large as for the primary outcome, were also larger than most caregiver studies conducted in the United States.⁸ One possible reason for the increased effect sizes in Vietnam may be attributable to the relative lack of knowledge, supports, and services available to family caregivers in Vietnam compared with the United States.

Although we also hypothesized that AD knowledge gain would be larger in the intervention group, both groups experienced a very modest knowledge gain, and there were no significant difference between groups. Our findings differ from studies conducted in the United States, which have found significant improvements in Alzheimer's knowledge as a result of multi-component interventions like REACH VN.⁸ One possible explanation for the lack of between group differences is that participants in both the intervention and enhanced control received education about AD. However, this does not explain the very modest gain in knowledge for both groups. The measure we used to assess Alzheimer's knowledge has been used in English and Vietnamese populations residing outside Vietnam who had higher levels of formal education compared with the caregivers in our study (mean of 7-8 years of formal education). The measure may need to be modified to be more suitable for caregivers with a lower level of formal education. Finally, the knowledge gained by caregivers (eg, skills in managing dementia-related behaviors, communicating with the person with dementia, and managing their own distress) may not be captured by the Alzheimer's knowledge scale, which focuses exclusively on the nature of the disease.

The intervention was feasible as well as efficacious. Our retention in the trial was 85%, and most of attrition was due to high mortality rates among the care recipients in the trial. The mortality rates in this study are comparable with another study conducted in India²⁷ and may be attributable to the advanced age of the care recipients, most of whom were living with moderate-to-severe dementia. At the cluster level, three clusters were dropped due to lack of insufficient recruitment. The reasons for the low recruitment in these clusters is less clear and may reflect lower levels of local interest, resources, and capacity to assist the research team in the recruitment process.

The interpretation of our results should consider several study limitations. The pilot cluster RCT was conducted in a semi-rural area in northern Vietnam, and caution should be used in generalizing these results to other settings, particularly urban areas, where the social and economic circumstances of older adults and family caregivers may be quite different. Inclusion of a knowledge scale that may not have been suitable for this population's lower literacy level is a second limitation of this study. Finally, our study is an

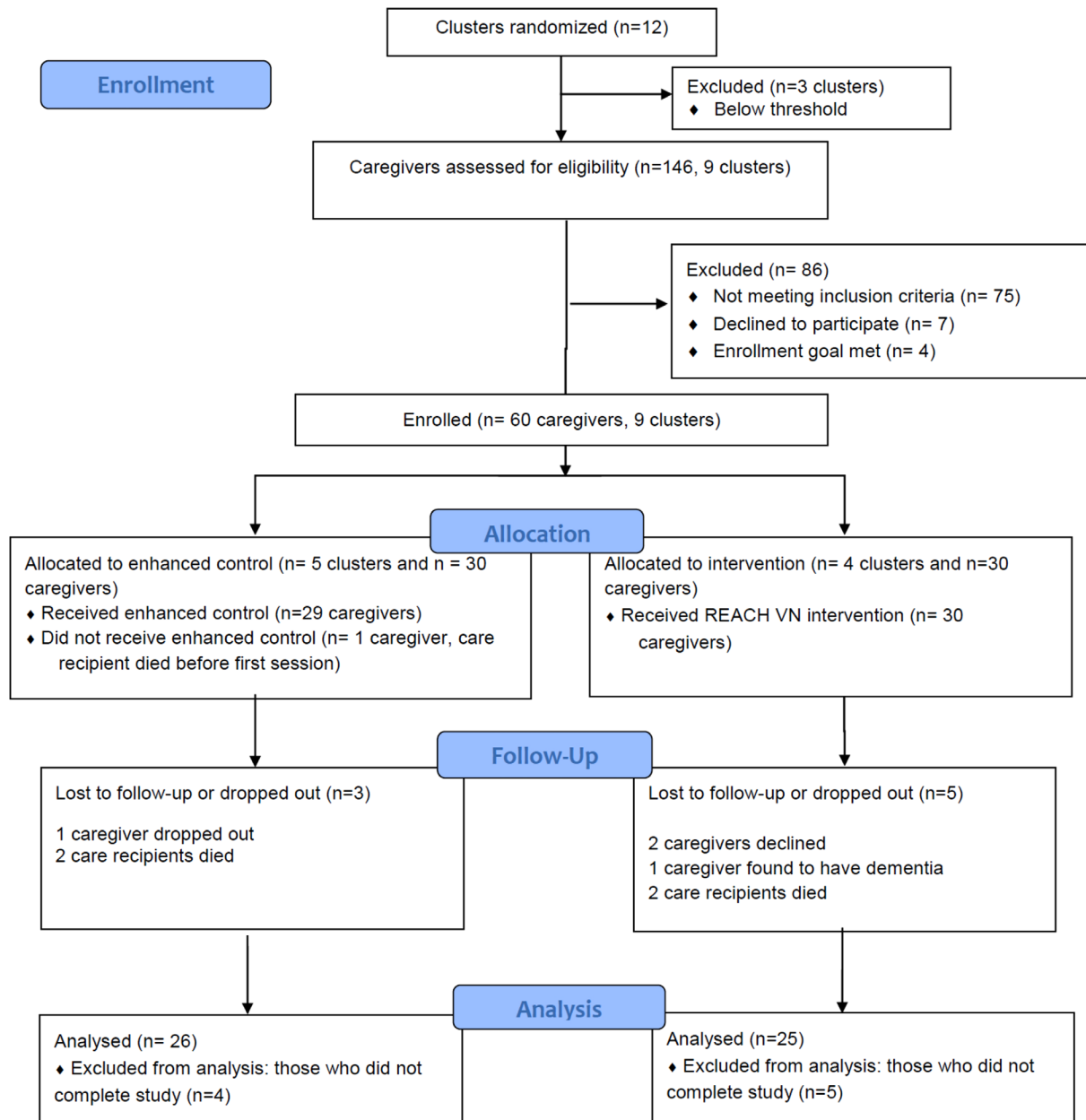


FIGURE 2 Consort diagram of recruitment for pilot cluster randomized controlled trial (RCT)

efficacy study in which the interventionists were highly trained social workers, doctors, and nurses from the Vietnam National Geriatric Hospital. To move toward a more scalable intervention model that is sustainable, future research is needed to determine if providers at the local level can be trained to deliver the intervention with fidelity and to achieve similar outcomes. Our study did not measure a number of variables that might be important to include in future studies in relationship to caregiver outcomes, including caregiver religion and socioeconomic status, as well as dementia type, medical comorbidities, and health insurance of the person living with dementia.

In conclusion, we found that a culturally adapted and relatively brief family caregiver intervention was both efficacious and feasible in Vietnam. These results may be relevant to other LMIC countries in

Asia that are facing growing numbers of older adults with dementia in the face of relatively little evidence about what community programs are effective. Our study suggests that with relatively modest cultural adaptation, multicomponent interventions developed in the United States may be effective for LMICs in Asia and perhaps elsewhere. Evidence already exists for the efficacy of multi-component interventions based on REACH and other models in HIC in Asia.⁴ Furthermore, REACH VN's relative brevity may enhance its sustainability in other lower resource settings. Although our findings clearly need replication in a larger study with more community-embeddedness, these results are promising for Vietnam and other LMICs with a pressing need to meet the challenge of providing community-based care and support to family caregivers of people living with dementia.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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