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Maintenance of Effects of the Home Environmental Skill-Building Program for Family Caregivers and Individuals With Alzheimer's Disease and Related Disorders

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Background. Few studies evaluate whether short-term intervention effects are maintained over time for families caring for persons with dementia. This article examines whether treatment effects found at 6 months following active treatment were sustained at 12 months for 127 family caregivers who participated in an occupational therapy intervention tested as part of the National Institutes of Health Resources for Enhancing Alzheimer's Caregiver Health (REACH) initiative.

Methods. A randomized two-group design was implemented with three assessment points: baseline, 6 months, and 12 months. Caregivers were randomly assigned to a usual care control group or intervention that consisted of six occupational therapy sessions to help families modify the environment to support daily function of the person with dementia and reduce caregiver burden. Following 6-month active treatment, a maintenance phase consisted of one home and three brief telephone sessions to reinforce strategy use and obtain closure. Noninferiority statistical analysis was used to evaluate whether intervention caregivers maintained treatment benefits from 6 to 12 months in comparison to controls.

Results. For the sample of 127 at 6 months, caregivers in intervention reported improved skills ($p = .028$), less need for help providing assistance ($p = .043$), and fewer behavioral occurrences ($p = .019$) compared to caregivers in control. At 12 months, caregiver affect improved ($p = .033$), and there was a trend for maintenance of skills and reduced behavioral occurrences, but not for other outcome measures.

Conclusion. An in-home skills training program helps sustain caregiver affect for those enrolled for more than 1 year. More frequent professional contact and ongoing skills training may be necessary to maintain other clinically important outcomes such as reduced upset with behaviors.

FAMILIES provide the primary support to persons with dementia at home over the course of the disease (1). Despite numerous caregiver intervention studies (2–4), with few exceptions, in-home skills training has not been systematically tested (5,6). Fewer still evaluate long-term benefits or whether intervention effects are sustained over time (7). Evaluating the staying power of intervention effects on clinically relevant outcomes is important in order to identify ways of helping families manage dementia as the disease progresses.

The Home Environmental Skill-building Program (ESP) was a randomized clinical trial of the National Institutes of Health Resources for Enhancing Alzheimer's Caregiver Health (REACH) initiative. In the ESP, occupational therapists provide caregivers with education, problem-solving and technical skills (task simplification, communication), and simple home modifications. The goal is to help caregivers modify the environment to support care recipient physical functioning and reduce behavioral occurrences as well as to reduce caregiver burden. Active treatment, consisting of five 90-minute home visits and one telephone session, occurs over 6 months. Maintenance, consisting of one home visit and three brief telephone sessions to reinforce strategy use and obtain closure, occurs over the subsequent 6 months (8).

As reported elsewhere, at 6 months, treatment effects for 190 caregivers included reduced upset with behaviors, receiving less help with daily care, and improved affect. Also found was a trend for greater use of effective management strategies and fewer behavioral occurrences, but these were not statistically significant (9–11).

This article reports the maintenance of these main treatment effects at 12 months. To evaluate maintenance, we use noninferiority testing, a statistical approach used in pharmacological and medical clinical trials. The noninferiority hypothesis is the one-sided hypothesis that the experimental therapy is either similar to or better than standard therapy (12, and see other articles in the same journal issue). In noninferiority testing, ''similar'' means not importantly worse and not importantly better. Thus, we define maintenance in two ways: as no important loss of 6-month treatment effects at 12 months (e.g., ''similar''); or as improvement from 6 to 12 months. We seek to evaluate whether caregivers in intervention retain an important portion of 6-month effects or improve from 6 to 12 months in comparison to controls. This approach is in contrast to traditional methodologies that seek to evaluate significant change in caregiver scores from baseline to 12 months. Rather, here we are interested in evaluating ''maintenance'' or whether the effects achieved at 6 months are retained at 12 months.

METHODS

Caregivers enrolled in the study had to live with the person with dementia, be 21 years or older, be caregiving for at least 6 months, and provide at least 4 hours of daily care to persons with one or more activity limitations and Mini-Mental Status Examination (MMSE, 13) scores less than 24 (14). Eligible caregivers signed an Institutional Review Board-approved consent form prior to the baseline interview. Following baseline, caregivers were stratified by relationship (spouse or nonspouse) and race (white or minority), randomly assigned to experimental or usual care control groups, and then interviewed at 6 and 12 months.

At 12 months, data were available for 127 caregivers representing 33% attrition ($n = 63$) from the 190 caregivers with 6-month data. Reasons for dropout included nursing home placement (23 caregivers), bereavement (20 caregivers), and discontinuance (20 caregivers). A comparison of caregivers with and without 12-month data revealed that more white ($n = 38$) than minority caregivers ($n = 25$; $X^2(1) = 9.26$, $p = .002$) and more caregivers of persons with greater dependence in activities of daily living (ADLs, $Z = -2.01$, $p = .044$) dropped out.

Measures

We examined five outcome measures for which large or statistically significant main treatment effects were found at 6 months for the 190 caregivers. Measures included occurrence of seven memory-related behaviors using the REACH modified Revised Memory and Problem Behavior Checklist (15,16), the single REACH vigilance item, Days Receiving ADL Help (''How many days in a week have other family members or friends not being paid provided help?''; 17), caregiver upset with the seven behaviors, the 19-item Task Management Strategy Index to assess skill enhancement (18), and a five-item index to assess affect ($\alpha = .86$). For this measure, caregivers rated each of five items (feeling calm, upset, overwhelmed, angry, things going your way) as to whether the affective item had become much worse, somewhat worse, stayed the same, improved somewhat, or improved a lot over the last month.

Data Analysis

Using chi-square and Wilcoxon rank-sum tests, we examined differences between caregivers with and without 12-month data and between treatment and control conditions. Six-month treatment effects for the 127-caregivers were examined by calculating adjusted mean differences for each outcome variable using as covariates the baseline value of the outcome measure, design variables (race and relationship), and care recipient age given a statistically significant difference between experimentals and controls in the 127 caregivers for this variable. The normality assumption for each dependent measure was examined using the distribution of residuals. For Days Receiving ADL Help, the residual distribution was skewed, and normality improved with a logarithmic transformation. Transformed results were converted to the original scale for reporting purposes.

To evaluate maintenance of 6-month treatment effects, we compared intervention and control groups on adjusted mean differences from 6 to 12 months for each outcome variable using the same procedures as for analyses of 6-month data, but without adjusting for baseline values of the outcome measures. We initially defined maintenance as no important change of effect from 6 to 12 months. Although no change is normally stated as the null hypothesis, in our case it must be part of the statistical alternative hypothesis given that we want to conclude no change in effect. Because statistical methods do not apply to an alternative hypothesis of a single value (zero change) with a null hypothesis of any nonzero change, we initially define the maintenance of effect hypothesis to be ''no important change in effect.'' For example, if at 12 months we retain 80% of the 6-month intervention effect, we would consider this as no important change and conclude maintenance.

It is also possible that intervention effects continue to increase from 6 to 12 months. If so, a test of no important change in treatment effect might fail to reject the null hypothesis. Because the ''no important change'' hypothesis is two-sided, this might penalize the intervention for delayed effects. Thus, we reformulated maintenance as one-sided and consider maintenance to be no important *loss* of effect. The statistical null hypothesis is that the loss of effect is important; the statistical alternative hypothesis is that the effect increases or stays the same, or that the loss of effect is not important.

To test the one-sided hypothesis of maintenance, we present 95% one-sided confidence bounds (one of the bounds of 90% two-sided intervals). For measures where larger values are positive, if the lower confidence bound was above the boundary of no important loss of effect, we could claim maintenance at the 5% level. Suppose we had a treatment effect (intervention-control difference) of 1.0 at 6 months. We might consider any change from 6 to 12 months of no more than a loss of 0.25 to be unimportant. We would then compute the lower confidence bound for the change from 6 to 12 months. If that lower bound was larger than -0.25, we could conclude maintenance. For measures where smaller values are positive, this is reversed. We would need to consider 95% upper confidence bounds and determine whether the confidence bound was below the boundary of no important loss of effect. Table 1 lists which of the upper and lower bounds is appropriate. Maintenance of change in the affect measure was analyzed differently (see Results) given its response categories.

RESULTS

Study participants were primarily female ($n = 100$; 78.7%), and nonspouses ($n = 82$; 64.6%); 47 (37%) were white, 77 (61%) were African American, and 3 (2%) self-identified as other. Most caregivers had a high school or higher education ($n = 99$; 77.9%), an average age of 60.8 ($SD = 13.53$), and had been caregiving for 4.3 years ($SD = 3.71$). Care recipients were mostly female ($n = 89$; 70.1%), with a mean MMSE score of 12.4 ($SD = 7.06$). There were no statistically significant differences between experimental and control group caregivers except for care recipient age (experimental = 79.2, $SD = 8.1$; control = 82.9, $SD = 6.9$).

Table 1. Maintenance of Treatment Effects for Experimental ($N = 65$) and Control ($N = 65$) Group Participants at 12 Months

	Experimental		Control						
	6 Months	12 Months	6 Months	12 Months	6 Months Effects		Retention of Effect at 12 Months		
Measure	*M*	*M*	*M*	*M*	Ratio of Adjusted Means at 6 Months*	*p* Value	Ratio of Adjusted Means†	One-Sided CI Lower	One-Sided CI Upper
Caregiver outcomes									
Days receiving ADL help‡	2.22§	2.41§	2.87§	2.62§	.77	**.043**	1.20		**1.52**
					Difference of Adjusted Means		Difference of Adjusted Means		
Upset with memory-related behaviors	4.76 (5.27)	4.61 (4.97)	5.19 (5.52)	4.0 (5.08)	−.76	.307	.69		**1.82**
Perceived change in affect	3.17 (.64)	3.11 (.70)	3.05 (.56)	2.89 (.60)	.13	.248	.11	—¶	
Task strategy use	3.07 (.56)	3.00 (.64)	2.85 (.56)	2.84 (.59)	.18	**.028**	−.06	**−.21**	
Care recipient outcome									
No. of behavioral occurrences	4.42 (1.53)	4.10 (1.80)	4.65 (1.69)	4.36 (1.68)	−.52	**.019**	.06		**.48**

Notes: *Adjusted for baseline value.

†Not adjusted for baseline value.

‡Analysis used base 10 log transformed scale.

§Geometric mean.

¶See text for explanation.

CI = confidence interval; *M* = mean; ADL = Activities of Daily Living.

Maintenance of Treatment Effects

For Days Receiving ADL Help (Table 1), we found a statistically significant effect at 6 months, with the mean number of days receiving help in the intervention group being 77% that of the mean number for controls ($p = .043$). Comparing 12- to 6-month results, intervention and control group scores move closer, representing a loss of intervention effect (Figure 1). Our upper confidence bound is 1.52; that is, a 52% increase over the 6-month ratio of 0.77. This corresponds to an intervention/control ratio of more than 1.0, a reversal of the initial 6-month intervention, and thus maintenance cannot be concluded.

The intervention effect for Upset with Memory-related Behaviors at 6 months was –.76 ($p = .307$), which was smaller than that found for the initial group of 190 caregivers (adjusted mean difference = –1.19, $p = .027$). The intervention-control comparison at 12 months essentially returned to baseline differences (Figure 2); again, this represented an important loss of the 6-month intervention effect; thus, we cannot conclude maintenance.

On the affect measure questionnaire, caregivers were asked to evaluate whether they improved, stayed the same, or deteriorated over the past month. This measure does not fit our basic approach to assessing maintenance, as a score of 3 refers to no change or staying the same in affective status, thus the score itself corresponds to maintenance. The affect measure showed a statistically significant effect in the 190 caregiver sample at 6 months (adjusted mean difference = 0.19, $p = .034$). However, for the 127 caregivers, we obtained a smaller and statistically nonsignificant 6-month effect (adjusted mean difference = 0.13, $p = .248$). Nevertheless,

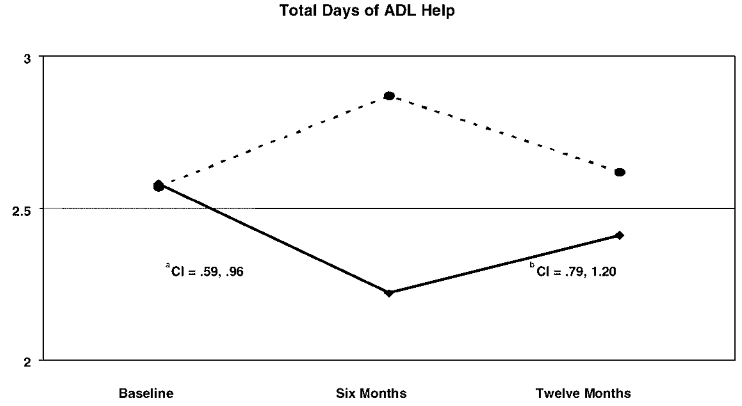

Figure 1. Mean (geometric) days of help with activities of daily living (ADLs). Dotted line = usual care; solid line = experimental; aCI = baseline – 6 months; bCI = baseline – 12 months.

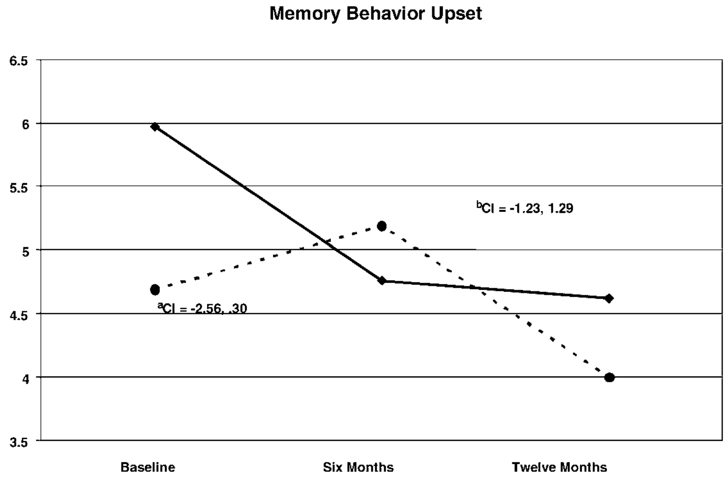

Figure 2. Mean level of upset with memory-related behaviors. Dotted line = usual care; solid line = experimental; ^{a}CI = baseline – 6 months; ^{b}CI = baseline – 12 months.

the experimental-control group difference continued to increase from 6 to 12 months so that, at 12 months, the difference of the adjusted means is 0.24 ($p = .033$) (Figure 3). Comparing the intervention group score at 12 months to a no-change score for the prior month of 3.0, we found significant improvement ($p = .033$). Thus, we conclude that intervention caregivers continue to show both affective improvement over time and more benefit than do controls. An effect of 0.20 corresponds to a one-point increase on one item for every experimental caregiver compared to controls. Given that items reflect subjective burden (upset), we consider this effect meaningful to those caregivers.

The Task Management Strategies Index showed a statistically significant effect at 6 months, with a difference of 0.18 ($p = .028$). This is a larger effect than was found for the 190-caregiver sample (adjusted mean difference = 0.12, $p = .073$). This effect represents a slightly better than one-point increase in use of any three items or, alternately, a three-point increase in use of one item for experimental caregivers compared to controls. This may be clinically meaningful and beneficial to those caregivers. By 12 months, intervention and control means were closer (Figure 4). Although the means suggest a trend toward maintenance, the lower confidence bound is –0.21, corresponding to slightly more than a complete loss of the 0.18 intervention effect. We do not conclude maintenance of effect.

The number of memory-related behavioral occurrences showed a larger intervention effect when analyzed here (adjusted mean difference = –0.52, $p = .019$) than for the 190-caregiver sample (adjusted mean difference = –0.27, $p = .119$). At 12 months, we had a similar intervention effect as at 6 months (Figure 5), suggesting an important maintenance of effect. An effect of –0.52 (6 months) or –0.48 (12 months) corresponds to one less behavior in one of every two intervention care recipients compared to controls, an important effect for these caregivers. The upper confidence bound is 0.48, a loss of about 90% of the effect seen at 6 months (0.52), corresponding to a remaining 12-month

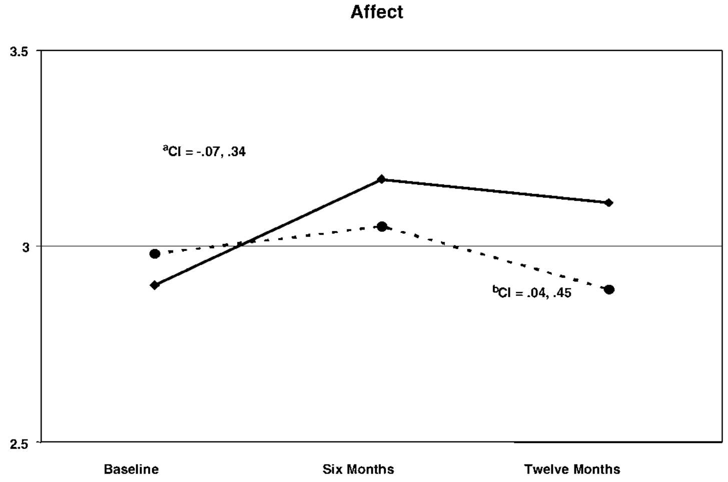

Figure 3. Mean level of affect. Dotted line = usual care; solid line = experimental; ^{a}CI = baseline – 6 months; ^{b}CI = baseline – 12 months.

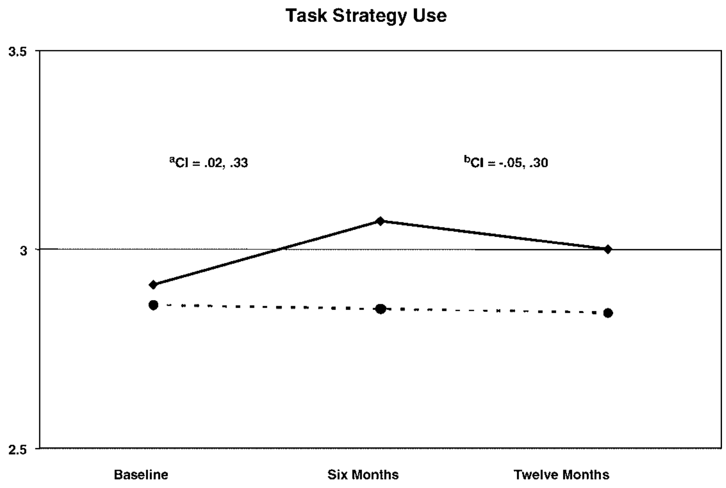

Figure 4. Mean level of task strategy use. Closed circles = usual care; closed diamonds = experimental; [a]CI = baseline – 6 months; [b]CI = baseline – 12 months.

effect of 0.04. The message here is mixed. A loss of 90% of the 6-month effect is important, so we cannot necessarily conclude maintenance. However, the 12-month effect of 0.04 corresponds to one additional loss of behavior in one of every 25 intervention care recipients compared to controls; this may be clinically significant due to the impact of these behaviors on caregivers. Also, the confidence interval is wide; thus, we may not have sufficient power to detect maintenance. The trend is in the right direction, but maintenance must be interpreted cautiously.

Discussion

We confirmed that important intervention benefits were achieved at 6 months for the 127 caregivers. Compared to controls, caregivers in the experimental group reported more use of effective strategies (skill enhancement), receiving less help for ADL assistance, and fewer behavioral occurrences. By 12 months, we found a further increase in improvement in caregiver affect, and a trend for maintenance in two other outcomes, effective strategy use and behavioral occurrences.

Given the lack of empirically derived cutoff points or consensus as to what constitutes meaningful change scores in caregiver measures, the determination of an important loss of treatment effect is necessarily qualitative and based on professional judgment (19). We would contend that the maintenance of effect in the experimental group compared to controls is clinically significant. Considering the negative health consequences of caregiver distress, even slight improvement in one affective item may represent a meaningful benefit.

Although we are unable to conclude maintenance in this study for other outcomes, the trend for experimental caregivers compared to controls to maintain a portion of their 6-month skill level and report reduced behavioral occurrences may be clinically meaningful. The trend suggests that experimental caregivers continued to use simplification

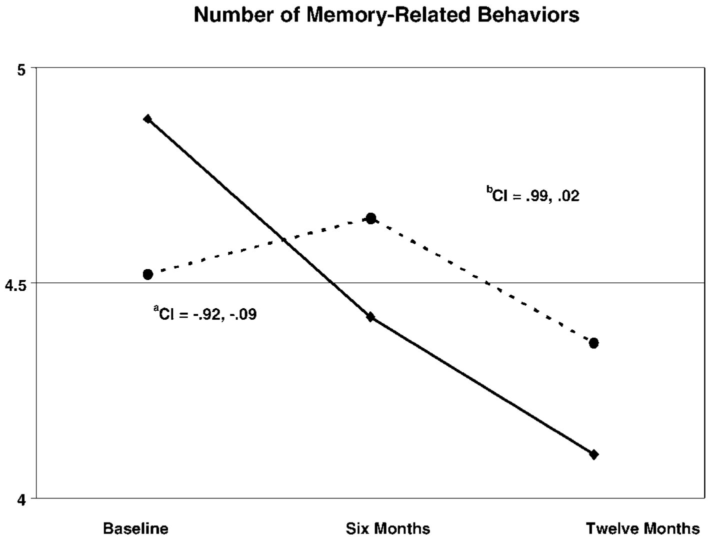

Figure 5. Mean number of memory-related behaviors. Closed circles = usual care; closed diamonds = experimental; [a]CI = baseline – 6 months; [b]CI = baseline – 12 months.

strategies that are designed to support care recipient daily functioning. Also, previous research has shown that behavioral occurrences can trigger nursing home placement. Thus, maintaining a reduction in behavioral occurrences over 12 months is important. One explanation for these outcomes may be that by enhancing skills, caregivers achieved a sense of personal control and feeling less overwhelmed (improved affect). Also, use of environmental and task-simplification skills to address problematic behaviors may have translated into fewer behavioral occurrences. Nevertheless, given the wide confidence intervals for strategy use and behavioral occurrence, caution is called for in interpreting maintenance, and more research is certainly warranted. It may be that for these two variables the reduced sample size resulted in loss of power to detect maintenance and a Type II error.

We did not find maintenance of effects for two outcomes, days receiving help and upset with behaviors. Most of the immediate benefits shown at 6 months had dissipated, and experimental and control caregivers showed similar declines for these variables.

The overall pattern of results is not straightforward or clear cut and raises critical issues for caregiver intervention research. For this sample of 127 caregivers, we see statistically significant intervention benefits at 6 months (e.g., reduced behavioral occurrences and skill enhancement) that were not found in the initial 190-caregiver sample, and we find support for maintenance for one outcome (affect) and a trend for two other outcomes (skill enhancement and behaviors). The modest maintenance of effects identified here are consistent with previous research. A recent meta-analytic review of 78 caregiver interventions (20) similarly found very modest effects for numerous outcomes in studies of dementia caregivers, with these studies reporting far fewer benefits than in studies of nondementia caregivers. Other research suggests that caregivers may require ongoing intense professional contact for benefits to be sustained over time (7).

There may be several reasons for our findings. First, the brief maintenance phase of the ESP may not be of sufficient intensity to maintain treatment gains in all domains. Second, effects may be context specific and of short duration. That is, ESP strategies (e.g., simplifying bathing routine) are customized to address specific concerns (e.g., resistance to bathing). A strategy may solve the presenting concern providing immediate caregiver relief. Nevertheless, a specific strategy may not be transferable to subsequent problems; thus beneficial outcomes may not be sustained in all areas. Alternately, there may be an adaptive mechanism such that caregivers derive immediate relief but, with time, return to previous upset levels as new problems emerge.

One recommendation based on this pattern of results is that interventions be developed and tested that enable long-term provider-caregiver contact of sufficient intensity to afford the support caregivers need with disease progression. This would require a flexible intervention and reimbursement approach to address new caregiver problems as they emerge over time with disease progression. Correspondingly, short-term interventions, such as the ESP, that are designed to address specific and immediate concerns at each point along the trajectory of caregiving might continue to have an important role in alleviating acute upset or burden associated with a specific stage of caregiving.

Another implication of these findings is that more attention needs to be given to sampling and selection issues in caregiver intervention research. In this study, 50% of the initial 255 caregivers enrolled at baseline were unavailable at 12 months. An important impact of the attrition is that all of our confidence intervals are wider than they otherwise would be. This corresponds to a loss of power to conclude maintenance at 12 months, particularly for the two outcomes for which there is a trend (skill enhancement and behavior occurrence). In addition, dropouts were more often caring for highly dependent persons. Our previous research suggests that caregivers of persons at the mild to moderate stage benefit from home environmental strategies more so than do caregivers of highly dependent persons, possibly accounting for their dropping out. To maximize benefits, study inclusion criteria should be tailored to match sample characteristics with interventions.

There was also a selection issue for three outcomes. We found a statistically significant 6-month effect for skill enhancement and behavioral occurrences for the 127 caregivers, but not for the initial 190 caregivers. For affect, we found a statistically significant 6-month effect for the 190 caregivers but not for the 127-caregiver sample. This suggests that those caregivers with only 6-month data may be different from those with 12-month data, posing a concern for generalizability. Those caregivers not available at 12 months were mostly white caregivers and those caring for highly dependent persons.

Finally, this study presents the non-inferiority model, which uses the concept of no important loss of effect to evaluate whether significant benefits are sustained over time. The application of this approach is dependent on consensus as to what constitutes clinical significance and maintenance of benefits that have practical, real-life consequences (21,22). Given that traditional caregiver measures lack empirically derived scores indicative of clinical significance, this approach is necessarily based on professional judgment as to what constitutes clinically significant sustained effects. Developing consensus as to what constitutes clinical significance and using statistical procedures such as non-inferiority testing to examine retention represent the next critical steps for advancing caregiver intervention research.

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