Research Article

Feasibility of Telehealth Occupational Therapy for Behavioral Symptoms of Adults With Dementia: Randomized Controlled Trial

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Importance: Supporting community residency of adults with Alzheimer's disease (AD) is a critical public health initiative. Occupational therapy can contribute to this goal.

Objective: To assess the feasibility of a novel telehealth intervention to support occupational engagement in community-residing people with AD.

Design: Single-blind, three-arm, parallel, randomized controlled trial.

Setting: Occupational therapy delivered through telehealth in participants' homes.

Participants: People with AD who reside in the community with behavioral symptoms and their care partners (dyads).

Interventions: (1) HARMONY (Helping older Adults cReate & Manage OccupatioNs successfully), a telehealth intervention that applies principles of individualized guided discovery with environmental cueing for caregivers of persons with AD to promote activity participation and manage behavioral symptoms; (2) standardized training regarding the use of a sensory-based approach in dementia care; and (3) a control, including home safety education and weekly monitoring of behaviors.

Outcomes and Measures: Feasibility was assessed as the primary outcome measured by completion of at least 75% of the telehealth sessions. Secondary outcomes included change in functional activity performance and neuropsychiatric behavioral symptoms.

Results: Twenty-eight dyads participated. The intervention was feasible, with high adherence to weekly visits (*M* number of visits = 5.4 for HARMONY, 4.9 for standardized training, and 4.6 for control), with high participant retention in the intervention arms. HARMONY demonstrated promise in improving patient performance and behavioral symptoms.

Conclusions and Relevance: HARMONY is feasibly delivered through telehealth service and has a positive effect on occupational performance and behavioral symptoms of AD. Additional studies are needed to explore effectiveness in a broader population.

What This Article Adds: Use of HARMONY for community-residing adults with AD is feasible and has promise for improving functional activity performance and behavioral symptoms, as well as caregiver satisfaction.

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The global prevalence of Alzheimer's disease (AD) and related dementias (ADRDs) is expected to triple in the next 30 yr (Alzheimer's Association, 2020). Behaviors and psychiatric symptoms of dementia (BPSDs) are present in nearly 90% of people diagnosed across the ADRD spectrum, including prodromal stages

(Lyketsos et al., 2002). Common BPSDs include apathy, depression, agitation, aggression, anxiety, and sleep disorders (Cerejeira et al., 2012). Such symptoms are associated with lessened functional activity engagement and increased caregiver burden, they lead to earlier institutional care, and they decrease the quality of life for the caregiver and the person with ADRD (Eska et al., 2013; Risco et al., 2015). National and international agencies recognize the need for nonpharmacological intervention as a first-line treatment (Kales et al., 2019). However, there are only a few frameworks and protocols to guide intervention, which severely limits real-world implementation (Butler et al., 2020). Care of Persons with Dementia in their Environments (COPE) was established in 2010 as an efficacious occupational therapy intervention for older adults with dementia residing in their homes (Gitlin et al., 2010). The COPE treatment plan provides 10 sessions with an occupational therapist to deliver caregiver training in modifications to the home environment, activities, communication, problem-solving, and stress reduction. COPE strengthened evidence supporting occupational therapy in home-based dementia care but does not address BPSDs beyond agitation and does not incorporate sensory processing theory as a mechanism of BPSD treatment. Additionally, the Tailored Activities Program (TAP) is a validated framework to reduce BPSDs through activities tailored to the capabilities of the person living with dementia (Gitlin et al., 2008). The TAP added evidence to support efficacy in the use of activity for dementia care, as well as the need for a tailored approach. Sensory-based interventions are increasingly used in ADRD care; however, evidence remains mixed because of methodological variability in implementation and lack of tailored approaches (Lorusso & Bosch, 2017). There is minimal evidence for sensory-based dementia interventions that have been designed by occupational therapists. Although studies have examined nonpharmacological interventions using elements of the environment, such as physical modifications, caregiver training, activity engagement, or sensory-based interventions, there is limited representation in the evidence for interventions integrating these aspects to promote optimal behavioral and occupational performance (Jensen & Padilla, 2017).

The Person–Environment–Occupation–Performance (PEOP) model describes transactional and constitutive aspects that must be present to support the person in their environment as it relates to adaptive behavior and occupational performance (Baum et al., 2015; Wahl et al., 2021). The model requires critical consideration of the intersection between environmental affordances and the person's functional performance capacity, particularly as adults with ADRD gradually lose the ability to cognitively initiate, plan, organize, sequence, and complete functional daily activities (Baum et al., 1993, 2008). The aging effects on neurological capacities to acquire environmental information also need to be considered. Peripheral sensory changes that occur with normative aging, such as presbyopia and presbycusis, can compromise messaging between the peripheral and central nervous systems. Furthermore, cortical processing of sensory information can be distorted secondary to ADRD pathology (Hwang et al., 2020). Maladaptive behavioral symptoms observed in ADRD can be attributed to incongruence between environmental affordance and central and peripheral neurological incapacities of the person (Kahana, 1982). Occupational therapy interventions, which promote congruence between the environment and personal capacities, facilitate occupational performance and influence BPSDs (Baum, 1995; Caspar et al., 2018).

Four key components should be considered in environmental, situationally focused intervention development for older adults with cognitive impairment (Rhodus & Rowles, 2022): tailored sensory-based environmental cueing; a person-centered approach emphasizing strengths, personal preferences, and autonomy while acknowledging the cognitive and physiological capacities of the person; individualized goal selection with occupational gradation; and care partners' capacity to support function and behavior. These concepts are integrated into a newly designed intervention program, HARMONY: Helping older Adults cReate & Manage OccupatioNs successfullY. The overarching aim is to promote functional activity engagement and decrease the behavioral symptom severity of ADRD for maximal quality of life and well-being for those living with ADRD and those caring for them.

The primary objective of the study described here was to assess the feasibility of the HARMONY intervention, specifically its delivery to community-dwelling older adults with AD and their care partners using telehealth, or videoconferencing, methods. Secondary objectives were to evaluate change in occupational performance and behavioral symptoms of dementia after the intervention.

Method

Trial Design

In this study. we used a single-blind, three-arm, parallel, randomized controlled design. Dyads (consisting of a person with AD and their primary caregiver) were enrolled from a single site and randomly assigned to the control arm, the standard intervention arm, or the HARMONY arm. Data were collected at baseline, postintervention (6 wk), and a 4-wk follow-up. All trial procedures were approved by the University of Kentucky Institutional Review Board and were posted on ClinicalTrials.gov (Identifier NCT04555616) before participant recruitment.

Participants

Adults diagnosed as having AD, with a Clinical Dementia Rating Scale (CDR) score of ≥1.0 (Hughes et al., 1982), who were living in the community with caregiver-identified behavioral disturbance were

recruited from the University of Kentucky Alzheimer's Disease Research Center (UKADRC; Schmitt et al., 2012). Researchers met with the UKADRC clinical care team (consisting of a neurologist, nurse practitioners, and social workers) weekly to discuss potential UKADRC participants with BPSD who could benefit from the intervention. Researchers contacted caregivers of the UKADRC participants for enrollment. Participants were included if they had a stable medical condition, had stable medication use for 1 mo before screening, did not participate in cognitive-based rehabilitation or occupational therapy, and had a willing care partner. Exclusion criteria were restriction to bed, physically violent behaviors, profound or total sensory loss, diagnosis of major mental illness, and use of investigational medication within 30 d of screening. Sample size was determined to assess the feasibility of the use of videoconferencing to deliver the intervention, defined as at least 75% attendance. It was anticipated that at least 80% of the participants would attend this minimum number of sessions in the intervention arms but that less than 20% in the control arm would attend, yielding 81.5% power for a χ^2 test based on 10 dyads per arm. A sample size of 30 dyads (10 per arm) was selected. Power analyses for secondary outcome measures were not performed. A randomization scheme was generated before recruitment initiation using randomized permuted blocks. Participants were assigned arm allocation on enrollment on the basis of consecutive order.

Procedure

Consent was obtained from the caregiver and the person with AD or their legally authorized representative. Baseline assessments included the CDR to confirm inclusion and the Adult Sensory Profile (ASP; Brown et al., 2001) to assess the sensory preferences of people with AD. The Zarit Burden Inventory (Zarit et al., 1980) was sent to caregivers by means of an online survey format. To complete baseline data collection, a rater who was blinded to group allocation completed the Neuropsychiatric Inventory Questionnaire (NPI–Q; Kaufer et al., 2000) by phone with the caregiver and completed the Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005) by means of videoconferencing with the person with AD facilitated by the caregiver. The MoCA was administered by means of a validated approach for telehealth application (DeYoung & Shenal, 2018). The interventionist completed the Canadian Occupational Performance Measure (COPM; Dedding et al., 2004) interview with the caregiver by videoconference. The occupation with the highest importance to the caregiver and lowest performance score for the person with AD was selected as the targeted goal and outcome.

Dyads engaged in six weekly 1-hr telehealth visits with the interventionist on Zoom. Caregivers were required for all visits and given the choice to have the person with AD present (e.g., caregivers often excused the person with AD if they were exhibiting high agitation or paranoia). A treatment manual guided weekly visits for each of the intervention arms. To assess the fidelity of intervention adherence, caregivers kept daily behavior journals to track behavioral symptoms, intervention tool use, and response of the person with AD. The COPM, Zarit Burden Inventory, NPI–Q, and MoCA were completed at postintervention and at 4-wk follow-up.

Intervention

Participants who received intervention engaged in visits that replicated an occupational therapy telehealth visit, whereas participants in the control arm engaged in an attention-control weekly videoconference with the interventionist.

Control Group

Caregivers received a two-page educational pamphlet describing safety for home environments. Caregivers were asked to complete daily behavior journal entries and participate in weekly videoconference calls with the interventionist to discuss the status of behavioral symptoms as an attention control.

Standard Environmental Design Protocol

Participants received scripted training for physical environment modification recommendations and caregiving techniques. General physical environment modification recommendations included decluttering the living space, reduction of background noise, increased natural light, accommodation for accessibility to the commode and areas for drinking and eating. Caregivers received training for calming demeanor (emotional contagion), needs-driven care to decrease onset of behavioral disruption, and use of an accepting and accommodating approach to behavioral disruption. Participants also received a kit with preselected sensorimotor tools by mail (for contents of the tool kit, see Supplemental Appendix Table A.1, available online with this article at https://research.aota.org/ajot). The tools were selected to activate seven sensory systems (auditory, visual, tactile, olfactory, gustatory, vestibular, and proprioceptive) with consideration to elicit a calming, sensory-enriched environment. Caregivers were asked to introduce the tools to the person with AD three times per day (morning, afternoon, and evening), lasting a total of 30 to 60 min/day. It was recommended that no one tool be provided for more than 20 min at a time. A daily intervention tracking log was completed by the caregiver to monitor usage of intervention implementation.

HARMONY Intervention

Participants received the standard protocol as described earlier. In addition, therapists engaged caregivers through guided discovery (Overholser, 2013)

Table 1. Description of Outcome Measures

Outcome Measure	Description and Study Use	Psychometric Properties	Timing
Adult Sensory Profile (ASP)	A 60-item survey completed by the caregiver, who answers on the basis of the observed behaviors and preferences of the person with Alzheimer's disease (AD). Items are categorized in one of four sensory processing patterns (15 items each): low registration, sensation seeking, sensory sensitivity, and sensation avoiding. The ASP was used to tailor individualized intervention development.	Validated in people with dementia and norm referenced (Chung, 2006)	Preintervention
Canadian Occupational Performance Measure (COPM)	The COPM is a client-centered, standardized outcome measure that identifies challenges in performance among three categories of occupation: self-care (personal care, functional mobility, and community management), productivity (paid/unpaid work, household management, and play/school), and leisure (quiet recreation, active recreation, and socialization). Caregivers were asked to rate the patient's performance level and their own satisfaction with the performance level for the selected activity using a Likert scale ranging from 1 (*lowest level*) to 10 (*highest level*).	COPM is a valid tool for use with home-residing older adults among multidisciplinary clinicians and researchers (Tuntland et al., 2016)	Preintervention, postintervention, and 4-wk follow-up
Clinical Dementia Rating (CDR)	The CDR was administered at screening by a certified tester to determine eligibility for enrollment. It is a structured interview protocol that assesses memory, orientation, judgment and problem-solving, community affairs, home and hobbies, and personal care. Scores are combined to obtain a composite score ranging from 0 (*no dementia*) to 3 (*severe cognitive impairment*).	Internationally recognized valid and reliable tool for determining stages of dementia (Morris et al., 1988)	Preintervention, postintervention, and 4-wk follow-up
Montreal Cognitive Assessment (MoCA)	The MoCA assesses attention and concentration, memory, language, conceptual thinking, calculations, and orientation. It was administered by videoconference to the person with AD with facilitation from the caregiver to set up the computer, provide needed testing materials, and sustain the engagement of the person with AD. Total possible score is 30 points; a score of ≥26 is considered normal.	Validated and reliable measure for people with dementia (Lyrakos et al., 2014) and for telehealth implementation (DeYoung & Shenal, 2018)	Preintervention, postintervention, and 4-wk follow-up
Neuropsychiatric Inventory Questionnaire (NPI–Q)	The NPI–Q assesses 12 behavioral and psychiatric domains (delusions, hallucinations, irritability, anxiety, agitation, depressions, dysphoria, apathy, disinhibition, aberrant motor behavior, appetite/eating changes, and nighttime behavior). The caregiver rates each behavior that is present for severity in the patient (1 = *mild*, 2 = *moderate*, and 3 = *severe*) and distress to the caregiver (ranging from 0 = *not distressing at all* to 5 = *extreme or very distressing*).	Established high validity in use by telehealth application (Camozzato et al., 2015)	Preintervention, postintervention, and 4-wk follow-up

(*Continued*)

Table 1. Description of Outcome Measures (*Cont.*)

Outcome Measure	Description and Study Use	Psychometric Properties	Timing
Zarit Burden Interview	A 22-question interview that assesses the burden of providing care rated by the caregiver. Each item is rated on a scale: 0 = *never*, 1 = *rarely*, 2 = *sometimes*, 3 = *quite frequently*, and 4 = *nearly always*.	Valid and reliable tool for use with caregivers of persons with dementia (Hébert et al., 2000)	Preintervention, postintervention, and 4-wk follow-up

on the basis of standardized assessment (COPM and ASP) results to encourage caregivers to self-identify elements in the home environment and situational contexts that support behavioral and occupational needs. Caregivers were provided training with regard to the mechanisms of sensory processing in relation to aging and AD, followed by additional prompts for self-discovery to identify areas for environmental cues to encourage activity participation and behavioral regulation for participants with AD. The individualized sensory protocol used the ASP and COPM results to incorporate personal preference and behavioral presentation for selection of sensory activities, as well as temporality and occupation for implementation. Four characteristics of sensory input (intensity, speed, amount, and predictability and familiarity) were manipulated on the basis of a predetermined decision matrix to alter behavioral responses with respect to individual neurological threshold and behavior. For example, people with predominate sensory processing preferences in low registration and sensation-seeking quadrants received sensory activities to increase alertness, and those in sensory sensitivity and sensation-avoiding quadrants received sensory activities related to calming. Participants were provided sensory kits that were tailored for these needs on the basis of preferred sensory stimuli (as determined by the ASP) and matched environmental cues that are needed to support occupation and behavioral regulation. For example, a participant with chronic skin picking received three silicone skin brushes, which the caregiver placed in areas where the participant exhibited the most frequent picking behavior.

Outcomes

Feasibility was measured on the basis of 75% attendance to weekly videoconferences. To maintain fidelity, we reviewed journal entries weekly, as well as the sensory tool technique. Secondary outcomes (Table 1) included change in performance of functional activity for the person with AD measured by the COPM and change in behavioral symptoms measured by the NPI–Q. Additional exploratory outcomes (Table 1) included cognitive functioning (MoCA), caregiver satisfaction (COPM), and caregiver burden (Zarit Burden Inventory). Single blinding was used during data collection for secondary and exploratory outcomes.

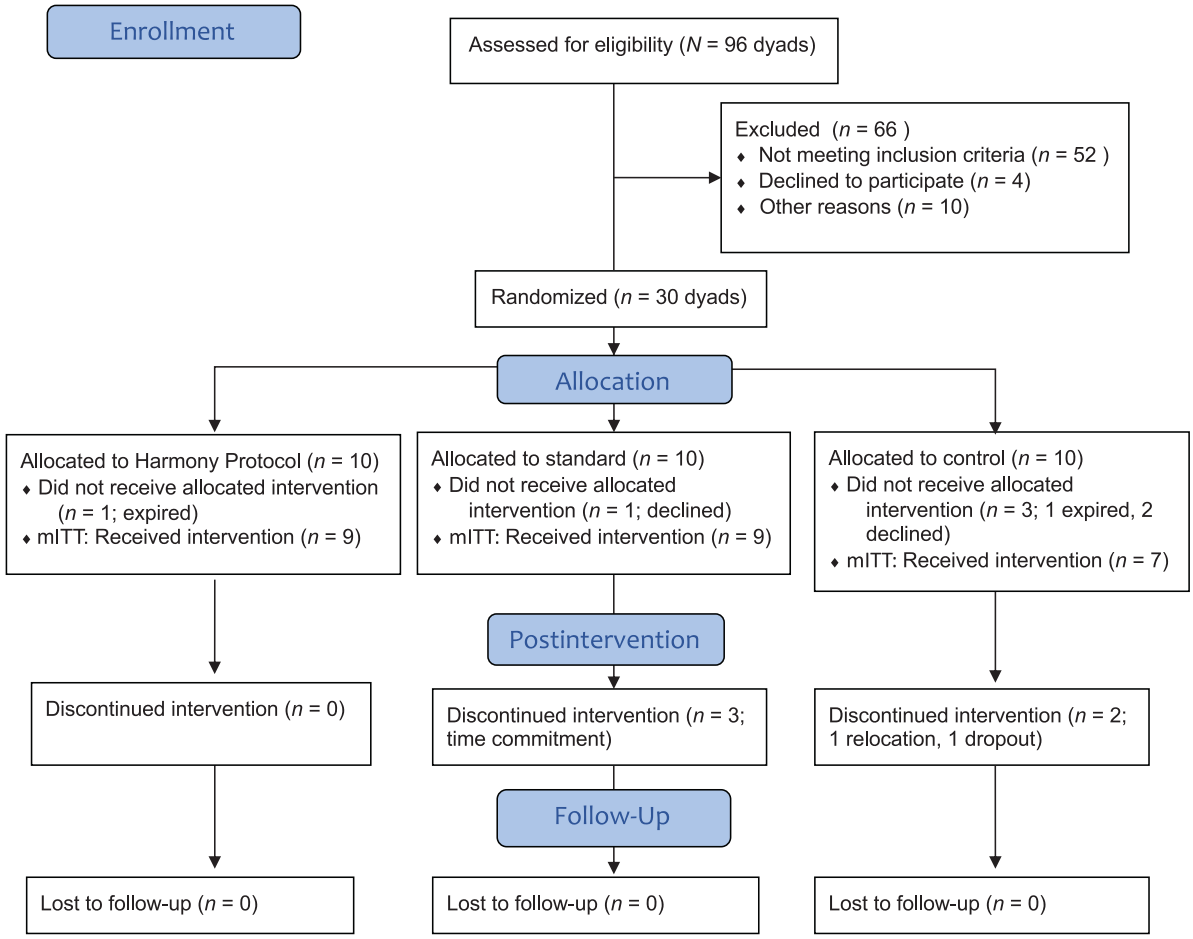
Statistical Methods

Participants' characteristics were compared among the three arms using analysis of variance (ANOVA) for continuous measures and a χ^2 test or Fisher's exact test for categorical measures. The analysis of the primary endpoint used a χ^2 test to compare the proportion of participants completing at least 75% of the video sessions among the study arms. The analysis of all secondary and exploratory endpoints relied on a modified intention-to-treat (mITT) strategy in which participants were included in the analysis only if the dyad completed at least one video session. For those endpoints, the main analysis tool was an analysis of covariance (ANCOVA) in which the mean value of an endpoint at the end of the intervention period was adjusted for baseline and then compared among the study arms. Sensitivity analyses were conducted in which multiple imputation was used for missing responses at the end of the intervention period (regressed on baseline) and in which the list of covariates included age of the person with AD at baseline and gender of the caregiver, when appropriate. These sensitivity analyses did not change any of the conclusions drawn from the reported ANCOVA (shown later in Table 3) and are not reported here. A further sensitivity analysis included the measurements made at the 4-wk follow-up and relied on an ANCOVA to compare the profile of responses at the end of the intervention and at the 4-wk follow-up, each adjusted for baseline. This analysis did not change the conclusions drawn from Table 3 and is not reported here. All analyses were conducted using PC SAS (Version 9.4).

Results

Of the 96 dyads who were assessed for eligibility, 30 agreed to participate (see CONSORT diagram in Figure 1). The dyad characteristics that were assessed included age, gender, education, race, and length of relationship (Table 2). Age of the person living with dementia ($p = .014$) and caregiver gender ($p = .0029$) varied among groups. The primary outcome demonstrates that the intervention is feasible, with high adherence to weekly visits ($p = .061$). Seven of 10 dyads in the HARMONY arm completed at least 75% of the telehealth sessions. Six of 10 dyads in the standard arm attended at least 75% of the telehealth sessions, and 2 of the 10 dyads in the control arm attended at least 75% of the telehealth sessions. Additionally, this

Figure 1. Consolidated Standards of Reporting Trials flow diagram.



Note. All numbers represent dyads (person with dementia and their care partner). mITT = modified intention to treat.

feasibility trial identified several characteristics required for advancing the intervention toward larger clinical studies (Tickle-Degnen, 2013). Assessment of resources confirms utility of multi-disciplinary teams for recruitment of community-residing adults with dementia and their caregivers. However, internet access and comfort with the use of videoconferencing technology was noted as challenging for some participants. Assessment of management of this feasibility trial identifies the benefit of REDCap as a data collection tool that was used in a manner similar to that of electronic medical record point-of-service documentation. REDCap was also structured in this study to manage appointment dates and study progression for all participants. Furthermore, we noted that there were no adverse events related to the intervention. However, reports of falls, infection, and unrelated exacerbation of comorbid conditions were noted among 6 participants.

Secondary outcomes included change in neuropsychiatric symptoms (severity and distress) and change in patient performance identified by care partners during functional daily activity (Table 3). Exploratory outcomes assessed change in caregiver satisfaction, change in caregiver burden, and change in cognition. Similarly, both secondary and exploratory outcomes identified the greatest improvement in the HARMONY protocol arm.

Discussion

The novel occupational therapy intervention described here incorporates elements of PEOP and sensory-based approaches to improve behavior and functional activity participation in older adults with ADRDs living in the community. Findings demonstrate feasibility of the intervention delivered by means of telehealth services with caregiver facilitation. Improvement in behavioral symptom severity and caregiver distress were observed that were consistent with the findings of prior studies that demonstrated the utility of occupational therapy in dementia care (Gitlin et al., 2018).

The COPM identified tasks with low performance by the person with AD. This allowed the interventionist to integrate an individualized, person-centered approach and tailor the intervention to the needs of the situation (Rhodus & Rowles, 2022). Delivery of the intervention was tailored through a lens of mediated learning using guided discovery principles (Overholser, 2013). This approach allowed care partners to self-identify environmental constructs to adapt and to increase their confidence. Interventions incorporated

Table 2. Participant Characteristics

Participant Characteristic	Total	Intervention Arm			p[a]
		HARMONY	Standardized	Control	
No. of dyads	30	10	10	10	—
Age, yr, *M* (*SD*), *n*					
PLWD	77.9 (7.9), 22	73.3 (7.1), 9	84.3 (5.4), 7	77.2 (7.4), 6	.014
Caregiver	69.0 (11.7), 22	69.7 (11.7), 9	67.7 (11.6), 7	69.5 (14.0), 6	.95
Gender, female/male, *n*					
PLWD	19/11 (30)	8/2 (10)	7/3 (10)	6/4 (10)	.25
Caregiver	19/11 (30)	2/8 (10)	8/2 (10)	9/1 (10)	.0029
Race, White/Black, *n*					
PLWD	29/1 (30)	10/0 (10)	10/0 (10)	9/1 (10)	1
Caregiver	29/1 (30)	10/0 (10)	10/0 (10)	9/1 (10)	1
Education, yr, *M* (*SD*), *n*					
PLWD	15.0 (2.4), 23	15.6 (2.0), 9	14.6 (2.1), 7	14.7 (3.2), 7	.69
Caregiver	16.3 (2.2), 25	17.0 (2.4), 10	16.3 (1.6), 8	15.3 (2.5), 7	.30
Length of caregiving relationship, yr, *M* (*SD*), *n*	4.4 (3.5), 20	5.6 (3.9), 8	3.3 (2.9), 5	3.7 (3.5), 7	.44
PLWD CDR, *M* (*SD*), *n*	2 (0.8), 24	1.9 (0.8), 8	2.0 (0.9), 9	2.1 (0.7), 7	.82
PLWD ASP abnormality, yes/no (*n*)	12/7 (19)	4/3 (7)	4/2 (6)	4/2 (6)	1

Note. ASP = Adult Sensory Profile; CDR = Clinical Dementia Rating; HARMONY = Helping older Adults cReate & Manage OccupatioNs successfullY; PLWD = person living with dementia.
[a]The *p* values are based on a one-way analysis of variance for continuous responses and on Fisher's exact test for categorical responses.

environmental features of the home, care partner training and facilitation of sensory stimulation, and a tailored focus on identified areas of occupation that were critical mechanisms for improving activity performance, consistent with the four tenets of the HARMONY program (Smallfield & Heckenlaible, 2017).

Care partners in this study expressed minimal concerns regarding the use of videoconferencing technology; however, troubleshooting was often required for initial sessions, which is similar to other studies (Gately et al., 2020). The literature suggests that caregivers of people with ADRDs have higher satisfaction and lower report of burden when adequately skilled in managing behaviors and engaging the person they care for in daily occupations (Baum, 1995; Lawton & Simon, 1968). Our exploratory outcomes are consistent with previous evidence. Care partners identified higher satisfaction specifically related to the targeted activity of intervention, they reported less burden, and they experienced less distress during behavioral symptoms. These findings, although exploratory, are important, because they demonstrate that the intervention did not increase burden—a concern when asking care partners to facilitate additional care tasks.

Occupational therapy has long recognized improved behavioral regulation after environmental and sensory-based interventions in people with autism spectrum disorder (ASD; Schoen et al., 2019). The intervention described here has parallels to pediatric sensory-based interventions (i.e., sensory diet) that are individualized and tailored to promote adaptive behavioral response. In this study, we applied similar mechanisms across the lifespan for older adults with ADRDs (Magnin, 2021). This may not be surprising, because recent evidence suggests similar behavioral sequelae between ASD, a neurodevelopmental disorder recognized in early childhood, and ADRDs, which are neurodegenerative conditions (Rhodus et al., 2020). Sensory-enriched environments within the home setting were associated with positive findings in this study. Implementation of this approach by means of telehealth increased outreach opportunities for broader implementation within rural and underserved environments (Gately et al., 2019; Possin et al., 2019). Evaluation and utilization of the home environment beyond historical approaches of safety and access have the potential to facilitate engagement tailored to functional cognition capacity (Baum et al., 2023). However, although this study combined several clinical assessments, the operationalization of individualized approach was complex. The development of assessments that consider a situational perspective (Rhodus & Rowles, 2022) by integrating PEOP and sensory approaches will dramatically advance the utility and clinical reproducibility of the intervention in real-world settings.

This study has limitations that should be noted. First, participant retention was much lower in the control arm compared with the HARMONY protocol

Table 3. Comparisons Among Groups for Identified Outcomes

Variable	Baseline, *M* (*SE*), *n*			Postintervention, *M* (*SE*), *n*			Cohen's *d*	*p*[a]
	HARMONY	Standardized	Control	HARMONY	Standardized	Control		
Primary Outcomes								
No. of completed visits	—	—	—	5.4	4.9	4.6	—	.61
No. of dropouts	—	—	—	1	2	3	—	.69
Secondary Outcomes								
PLWD performance	4.4 (0.8), 8	3.6 (0.8), 7	4.6 (0.4), 7	6.6 (0.9), 8	6.1 (1.1), 6	4.6 (2.5), 3	0.76	—
Behavioral symptom severity	10.3 (1.7), 7	9.8 (2.8), 6	13.3 (2.3), 6	8.4 (1.7), 6	10.8 (1.9), 5	8.9 (2.5), 3	0.55	—
Caregiver distress	10.9 (2.7), 7	13.3 (2.9), 6	19.3 (4.2), 6	10.0 (3.1), 6	11.4 (3.3), 5	10.0 (4.3), 3		—
Exploratory Outcomes								
COPM, caregiver satisfaction	3.8 (0.7), 8	4.7 (0.8), 7	5.3 (1.0), 7	7.5 (0.8), 8	6.0 (0.9), 6	3.4 (1.3), 3	1.86	—
PLWD MoCA	8.6 (3.7), 7	14.0 (2.9), 6	11.5 (11.5), 2	10.2 (1.2), 6	8.2 (1.5), 4	10.9 (2.1), 2	0.93	—
Zarit Burden Inventory, caregiver burden	28.4 (4.0), 9	28.9 (3.3), 7	26.6 (5.3), 7	26.3 (2.8), 8	31.0 (3.3), 6	27.9 (4.6), 3	0.59	—

Note. Means in the postintervention cells are adjusted for baseline obtained by analysis of covariance [ANCOVA]). COPM = Canadian Occupational Performance Measure; HARMONY = Helping older Adults cReate & Manage OccupatioNs successfully; MoCA = Montreal Cognitive Assessment; PLWD = person living with dementia.

[a]The *p* values for comparing the adjusted means are based on ANCOVA, with statistical significance determined by $p < .05$.

arm, limiting data collection at postintervention and follow-up. This could indicate the need for the intervention, it could indicate lack of perceived benefit of participation of the control arm, or it could be due to differences in the arms related to the age and gender of the caregiver. In the HARMONY arm, the mean age for the person with dementia was 73 yr, compared with the mean ages 84 yr and 77 yr in the standardized and control arms, respectively. Older age may indicate more years of caregiving needs. The HARMONY arm caregivers were predominately male, whereas the standard and control arm caregivers were predominantly female. This may also influence retention, because female caregivers often have additional responsibilities for caring and home management in this generation of older adults. Future research could include occupational profiles of caregivers to better describe influential mechanisms involved in caregiving for this intervention. Furthermore, the dropout influenced sample size and power. However, use of the mITT approach with multiple imputations allowed for proper statistical analyses. The findings of this study will improve sample size calculations for future trials.

Second, limitations to use of technology were observed. Inclusion criteria required participants to have access to internet and videoconferencing, and this approach did deter some people from participation. Lack of devices, lack of internet access, or discomfort with use of the videoconferencing platform were reported during recruitment. Reliance on personal devices and internet also affected communication, which was particularly noted during cognitive assessments. The timed portion of the MoCA was challenging because of differences in internet speeds, which limited real-time processing. Utilization of telehealth with care partners caused some participants with AD to be disturbed. One care partner reported increased hallucinations in the person with AD immediately after the telehealth visits. Another person reported an inability to distract his loved one during the telehealth visits and dropped out of the study because of the time commitment without additional help to care for his loved one. These components were critical for improving and adapting the intervention for the next phase of efficacy trials. Considerations, such as sending headphones, will also be implemented to decrease disturbance for the person with AD during telehealth visits.

Finally, effects of the intervention on behavior and occupational performance were secondary and exploratory outcomes. Future trials with appropriate sample sizes will identify mechanisms of action specific to the HARMONY protocol and further the progress of the development, future implementation, and clinical utilization of this telehealth intervention program. We also note that occupational therapy delivered by means of telehealth was expanded in 2020 because of the coronavirus disease 2019 (COVID-19) pandemic and the increase in services by the Centers for Medicare and Medicaid Services under the public health emergency. At the time of publication of this article, telehealth occupational therapy services have yet to become a permanent service option. The findings of this clinical trial support the feasibility, utility, and benefits of telehealth services provided by occupational therapists for older adults living with dementia and their care providers.

Implications for Occupational Therapy Practice

The findings of this study have several implications for occupational therapy practice:

- Individualized sensory-based intervention is feasibly delivered through telehealth and has a positive effect on performance and behavioral symptoms of people with AD.
- Additional research is needed with larger sample sizes to assess the generalizability of these findings.
- These findings highlight unique contributions of occupational therapy telehealth strategies in the home setting for older adults with AD. Such use may have similar mechanisms as used in pediatric practice.

Conclusions

The HARMONY occupational therapy intervention is feasible when applied through telehealth for community-residing older adults living with AD. Additional studies should be appropriately powered to explore the effectiveness of this intervention on secondary and exploratory endpoints, such as caregiver burden, cognition, and occupational performance. Once efficacy is established, this intervention has the potential to harness specific environmental and situational elements of individual ADRD care and is likely to decrease burdensome BSPDs and the need for institutional care, as well as possibly delaying mortality while preserving quality of life. Given the scope of the problems being managed, occupational therapy scientists have the opportunity to focus attention on the implications of such nonpharmacological interventions that are related to declining avoidable services and lowered health care costs, including delayed residency in facility-based care, lowered utility of emergent services, decreased falls, and sustained health of care partners.

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References

Alzheimer's Association. (2020). 2020 Alzheimer's disease facts and figures. *Alzheimer's and Dementia, 16,* 391–460. https://doi.org/10.1002/alz.12068

Baum, C. M. (1995). The contribution of occupation to function in persons with Alzheimer's disease. *Journal of Occupational Science, 2,* 59–67. https://doi.org/10.1080/14427591.1995.9686396

Baum, C. M., Christiansen, C. H., & Bass, J. D. (2015). The Person–Environment–Occupation–Performance (PEOP) model. In C. H. Christiansen, C. M. Baum, & J. D. Bass (Eds.), *Occupational therapy: Performance, participation, and well-being* (pp. 49–56). SLACK.

Baum, C. M., Connor, L. T., Morrison, T., Hahn, M., Dromerick, A. W., & Edwards, D. F. (2008). Reliability, validity, and clinical utility of the Executive Function Performance Test: A measure of executive function in a sample of people with stroke. *American Journal of Occupational Therapy, 62,* 446–455. https://doi.org/10.5014/ajot.62.4.446

Baum, C., Edwards, D. F., & Morrow-Howell, N. (1993). Identification and measurement of productive behaviors in senile dementia of the Alzheimer type. *Gerontologist, 33,* 403–408. https://doi.org/10.1093/geront/33.3.403

Baum, C. M., Lau, S. C. L., Heinemann, A. W., & Connor, L. T. (2023). Functional cognition: Distinct from fluid and crystallized cognition? *American Journal of Occupational Therapy, 77,* 7703205020. https://doi.org/10.5014/ajot.2023.050010

Brown, C., Tollefson, N., Dunn, W., Cromwell, R., & Filion, D. (2001). The Adult Sensory Profile: Measuring patterns of sensory processing. *American Journal of Occupational Therapy, 55,* 75–82. https://doi.org/10.5014/ajot.55.1.75

Butler, M., Gaugler, J., Talley, K., Abdi, H., Desai, P., Duval, S., . . . Yeshi, L. (2020). *Care interventions for people living with dementia and their caregivers* (Comparative Effectiveness Review No. 231; AHRQ Publication No. 20-EHC023). Agency for Healthcare Research and Quality. https://doi.org/10.23970/AHRQEPCCER231

Camozzato, A. L., Godinho, C., Kochhann, R., Massochini, G., & Chaves, M. L. (2015). Validity of the Brazilian version of the Neuropsychiatric Inventory Questionnaire (NPI–Q). *Arquivos de Neuro-Psiquiatria, 73,* 41–45. https://doi.org/10.1590/0004-282X20140177

Caspar, S., Davis, E. D., Douziech, A., & Scott, D. R. (2018). Nonpharmacological management of behavioral and psychological symptoms of dementia: What works, in what circumstances, and why? *Innovation in Aging, 2,* igy001. https://doi.org/10.1093/geroni/igy001

Cerejeira, J., Lagarto, L., & Mukaetova-Ladinska, E. (2012). Behavioral and psychological symptoms of dementia. *Frontiers in Neurology, 3,* 73. https://doi.org/10.3389/fneur.2012.00073

Chung, J. (2006). Measuring sensory processing patterns of older Chinese people: Psychometric validation of the Adult Sensory Profile. *Aging and Mental Health, 10,* 648–655. https://doi.org/10.1080/13607860600648080

Dedding, C., Cardol, M., Eyssen, I. C. J. M., & Beelen, A. (2004). Validity of the Canadian Occupational Performance Measure: A client-centred outcome measurement. *Clinical Rehabilitation, 18,* 660–667. https://doi.org/10.1191/0269215504cr746oa

DeYoung, N., & Shenal, B. V. (2018). The reliability of the Montreal Cognitive Assessment using telehealth in a rural setting with veterans. *Journal of Telemedicine and Telecare, 25,* 197–203. https://doi.org/10.1177/1357633X17752030

Eska, K., Graessel, E., Donath, C., Schwarzkopf, L., Lauterberg, J., & Holle, R. (2013). Predictors of institutionalization of dementia patients in mild and moderate stages: A 4-year prospective analysis. *Dementia and Geriatric Cognitive Disorders: Extra, 3,* 426–445. https://doi.org/10.1159/000355079

Gately, M. E., Tickle-Degnen, L., Trudeau, S. A., Ward, N., Ladin, K., & Moo, L. R. (2020). Caregiver satisfaction with a video telehealth home safety evaluation for dementia. *International Journal of Telerehabilitation, 12,* 35–42. https://doi.org/10.5195/ijt.2020.6337

Gately, M. E., Trudeau, S. A., & Moo, L. R. (2019). Feasibility of telehealth-delivered home safety evaluations for caregivers of clients with dementia. *OTJR: Occupation, Participation and Health, 40,* 42–49. https://doi.org/10.1177/1539449219859935

Gitlin, L. N., Arthur, P., Piersol, C., Hessels, V., Wu, S. S., Dai, Y., & Mann, W. C. (2018). Targeting behavioral symptoms and functional decline in dementia: A randomized clinical trial. *Journal of the American Geriatrics Society, 66,* 339–345. https://doi.org/10.1111/jgs.15194

Gitlin, L. N., Winter, L., Burke, J., Chernett, N., Dennis, M. P., & Hauck, W. W. (2008). Tailored activities to manage neuropsychiatric behaviors in persons with dementia and reduce caregiver burden: A randomized pilot study. *American Journal of Geriatric Psychiatry, 16,* 229–239. https://doi.org/10.1097/01.JGP.0000300629.35408.94

Gitlin, L. N., Winter, L., Dennis, M. P., Hodgson, N., & Hauck, W. W. (2010). A biobehavioral home-based intervention and the well-being of patients with dementia and their caregivers: The COPE randomized trial. *JAMA, 304,* 983–991. https://doi.org/10.1001/jama.2010.1253

Hébert, R., Bravo, G., & Préville, M. (2000). Reliability, validity and reference values of the Zarit Burden Interview for assessing informal caregivers of community-dwelling older persons with dementia. *Canadian Journal on Aging, 19,* 494–507. https://doi.org/10.1017/S0714980800012484

Hughes, C. P., Berg, L., Danziger, W. L., Coben, L. A., & Martin, R. L. (1982). A new clinical scale for the staging of dementia. *British Journal of Psychiatry, 140,* 566–572.

Hwang, P. H., Longstreth Jr., W. T., Brenowitz, W. D., Thielke, S. M., Lopez, O. L., Francis, C. E., . . . Fitzpatrick, A. L. (2020). Dual sensory impairment in older adults and risk of dementia from the GEM Study. *Alzheimer's and Dementia: Diagnosis, Assessment and Disease Monitoring, 12,* e12054. https://doi.org/10.1002/dad2.12054

Jensen, L., & Padilla, R. (2017). Effectiveness of environment-based interventions that address behavior, perception, and falls in people with Alzheimer's disease and related major neurocognitive disorders: A systematic review. *American Journal of Occupational Therapy, 71,* 7105180010. https://doi.org/10.5014/ajot.2017.027409

Kahana, E. (1982). A congruence model of person-environment interactions. In M. P. Lawton, P. G. Windley, & T. O. Byerts (Eds.), *Aging and the environment: Theoretical approaches* (pp. 97–120). Springer.

Kales, H. C., Lyketsos, C. G., Miller, E. M., & Ballard, C. (2019). Management of behavioral and psychological symptoms in people with Alzheimer's disease: An international Delphi consensus. *International Psychogeriatrics, 31,* 83–90. https://doi.org/10.1017/S1041610218000534

Kaufer, D. I., Cummings, J. L., Ketchel, P., Smith, V., MacMillan, A., Shelley, T., . . . DeKosky, S. T. (2000). Validation of the NPI–Q, a Brief Clinical Form of the Neuropsychiatric Inventory. *Journal of*

Neuropsychiatry and Clinical Neurosciences, 12, 233–239. https://doi.org/10.1176/jnp.12.2.233

Lawton, M. P., & Simon, B. (1968). The ecology of social relationships in housing for the elderly. *Gerontologist, 8,* 108–115. https://doi.org/10.1093/geront/8.2.108

Lorusso, L. N., & Bosch, S. J. (2017). Impact of multisensory environments on behavior for people with dementia: A systematic literature review. *Gerontologist, 58,* gnw168. https://doi.org/10.1093/geront/gnw168

Lyketsos, C. G., Lopez, O., Jones, B., Fitzpatrick, A. L., Breitner, J., & DeKosky, S. (2002). Prevalence of neuropsychiatric symptoms in dementia and mild cognitive impairment: Results from the Cardiovascular Health Study. *JAMA, 288,* 1475–1483. https://doi.org/10.1001/jama.288.12.1475

Lyrakos, G., Ypofandi, M., & Tzanne, P. (2014). EPA-1593—Psychometric and clinometric properties of the Montreal Cognitive Assessment (MoCA) in a Greek sample. *European Psychiatry, 29*(Suppl. 1), 1. https://doi.org/10.1016/S0924-9338(14)78748-6

Magnin, E. (2021). Neurodevelopmental and neurodegenerative similarities and interactions: A point of view about lifelong neurocognitive trajectories. *Journal of Alzheimer's Disease, 79,* 1397–1407. https://doi.org/10.3233/JAD-201207

Morris, J. C., McKeel, D. W. Jr., Fulling, K., Torack, R. M., & Berg, L. (1988). Validation of clinical diagnostic criteria for Alzheimer's disease. *Annals of Neurology, 24,* 17–22. https://doi.org/10.1002/ana.410240105

Nasreddine, Z. S., Phillips, N. A., Bédirian, V., Charbonneau, S., Whitehead, V., Collin, I., . . . Chertkow, H. (2005). The Montreal Cognitive Assessment, MoCA: A brief screening tool for mild cognitive impairment. *Journal of the American Geriatric Society, 53,* 695–699. https://doi.org/10.1111/j.1532-5415.2005.53221.x

Overholser, J. C. (2013). Guided discovery. *Journal of Contemporary Psychotherapy, 43,* 73–82. https://doi.org/10.1007/s10879-012-9229-1

Possin, K. L., Merrilees, J. J., Dulaney, S., Bonasera, S. J., Chiong, W., Lee, K., . . . Miller, B. L. (2019). Effect of collaborative dementia care via telephone and Internet on quality of life, caregiver well-being, and health care use: The Care Ecosystem randomized clinical trial. *JAMA Internal Medicine, 179,* 1658–1667. https://doi.org/10.1001/jamainternmed.2019.4101

Rhodus, E. K., Barber, J., Abner, E. L., Duff, D. M. C., Bardach, S. H., Caban-Holt, A., … Jicha, G. A. (2020). Behaviors characteristic of autism spectrum disorder in a geriatric cohort with mild cognitive impairment or early dementia. *Alzheimer Disease and Associated Disorders, 34,* 66–71. https://doi.org/10.1097/WAD.0000000000000345

Rhodus, E. K., & Rowles, G. D. (2022). Being in place: Toward a situational perspective on Care. *Gerontologist, 63,* gnac049. https://doi.org/10.1093/geront/gnac049

Risco, E., Cabrera, E., Jolley, D., Stephan, A., Karlsson, S., Verbeek, H., . . . Zabalegui, A. (2015). The association between physical dependency and the presence of neuropsychiatric symptoms, with the admission of people with dementia to a long-term care institution: A prospective observational cohort study. *International Journal of Nursing Studies, 52,* 980–987. https://doi.org/10.1016/j.ijnurstu.2015.02.013

Schmitt, F. A., Nelson, P. T., Abner, E., Scheff, S., Jicha, G. A., Smith, C., . . . Kryscio, R. J. (2012). University of Kentucky Sanders-Brown healthy brain aging volunteers: Donor characteristics, procedures and neuropathology. *Current Alzheimer Research, 9,* 724–733. https://doi.org/10.2174/156720512801322591

Schoen, S. A., Lane, S. J., Mailloux, Z., May-Benson, T., Parham, L. D., Smith Roley, S., & Schaaf, R. C. (2019). A systematic review of Ayres Sensory Integration intervention for children with autism. *Autism Research, 12,* 6–19. https://doi.org/10.1002/aur.2046

Smallfield, S., & Heckenlaible, C. (2017). Effectiveness of occupational therapy interventions to enhance occupational performance for adults with Alzheimer's disease and related major neurocognitive disorders: A systematic review. *American Journal of Occupational Therapy, 71,* 7105180010. https://doi.org/10.5014/ajot.2017.024752

Tickle-Degnen L. (2013). Nuts and bolts of conducting feasibility studies. *American Journal of Occupational Therapy, 67,* 171–176. https://doi.org/10.5014/ajot.2013.006270

Tuntland, H., Aaslund, M. K., Langeland, E., Espehaug, B., & Kjeken, I. (2016). Psychometric properties of the Canadian Occupational Performance Measure in home-dwelling older adults. *Journal of Multidisciplinary Healthcare, 9,* 411–423. https://doi.org/10.2147/JMDH.S113727

Wahl, H.-W., Hoppmann, C. A., Ram, N., & Gerstorf, D. (2021). Healthy aging-relevant goals: The role of person–context co-construction. *Journals of Gerontology, Series B: Psychological Sciences and Social Sciences, 76*(Suppl. 2), S181–S190. https://doi.org/10.1093/geronb/gbab089

Zarit, S. H., Reever, K. E., & Bach-Peterson, J. (1980). Relatives of the impaired elderly: Correlates of feelings of burden. *Gerontologist, 20,* 649–655. https://doi.org/10.1093/geront/20.6.649

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