

Environmental Correlates to Behavioral Health Outcomes in Alzheimer's Special Care Units

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Purpose: We systematically measured the associations between environmental design features of nursing home special care units and the incidence of aggression, agitation, social withdrawal, depression, and psychotic problems among persons living there who have Alzheimer's disease or a related disorder. **Design and Methods:** We developed and tested a model of critical health-related environmental design features in settings for people with Alzheimer's disease. We used hierarchical linear modeling statistical techniques to assess associations between seven environmental design features and behavioral health measures for 427 residents in 15 special care units. Behavioral health measures included the Cohen-Mansfield physical agitation, verbal agitation, and aggressive behavior scales, the Multidimensional Observation Scale for Elderly Subjects depression and social withdrawal scales, and BEHAVE-AD (psychotic symptom list) misidentification and paranoid delusions scales. Statistical controls were included for the influence of, among others, cognitive status, need for assistance with activities of daily living, prescription drug use, amount of Alzheimer's staff training, and staff-to-resident ratio. Although hierarchical linear modeling minimizes the risk of Type II—false positive—error, this exploratory study also pays special attention to avoiding Type I error—

the failure to recognize possible relationships between behavioral health characteristics and independent variables. **Results:** We found associations between each behavioral health measure and particular environmental design features, as well as between behavioral health measures and both resident and nonenvironmental facility variables. **Implications:** This research demonstrates the potential that environment has for contributing to the improvement of Alzheimer's symptoms. A balanced combination of pharmacologic, behavioral, and environmental approaches is likely to be most effective in improving the health, behavior, and quality of life of people with Alzheimer's disease.

Key Words: *Special care units, Environment, Alzheimer's disease, Nonpharmacologic treatment*

This study describes associations found between seven special care unit (SCU) environmental design features and agitation, aggression, depression, social withdrawal, and psychotic symptoms of residents with Alzheimer's disease in those SCUs. The measurable effect of environment on Alzheimer's symptoms is an important topic for all concerned with the care of persons with Alzheimer's disease—including family members, service providers, caregiving staff, doctors, other health care providers, architects, and developers. Even in the *New England Journal of Medicine* the case is made for environment as an intervention (Campion, 1996). Campion argued that therapeutic physical environments can positively affect the lives of residents with dementia: "Faced with a patient with progressive Alzheimer's disease, physicians may feel they can do nothing to help. This is wrong. . . . Care in a supportive environment can protect function for years" (p. 791).

This paper explores environmental treatment effects, using the conceptual model used by Beck and colleagues (1998) in their study of disruptive behavior in nursing homes. Beck's model presents disruptive behaviors as an outcome influenced both

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by individual factors such as gender, cognitive status, and health and by what the authors call “proximal factors,” intrapersonal as well as environmental. Attributes of both the physical and the social environment are included under the title of “environmental proximal factors.” Beck and colleagues identified these proximal factors but did not measure them, focusing instead on the influence of resident factors. This study measures proximal physical environment factors and statistically controls for the others.

Agitation, aggression, psychotic symptoms, depression, and social withdrawal were chosen as the dependent variables in this study because they occur frequently in Alzheimer’s SCUs and often lead to other difficult to manage behaviors. These challenging behaviors are often treated with costly medications that have multiple side effects. Whereas responses to control these behaviors in the past have included the use of physical restraints (Castle & Fogel, 1998), the passage of the Omnibus Budget Reconciliation Act (OBRA) and the resulting decline in the use of physical restraints has had the unintended consequence of increasing use of pharmacological restraints (Sloane et al., 1991).

For over a decade, numerous publications have discussed the treatment advantages of design features for this population (Calkins, 1988; Chafetz, & West, 1987; Coons, 1991; Hyde, 1989; Mathew, Sloane, Kirby, & Flood, 1988; Ohta & Ohta 1988; Weisman, Cohen, Ray, & Day, 1991; Zeisel, Hyde, & Levkoff, 1994). It is timely to carefully consider how environment can more humanely and cost-effectively contribute to managing and reducing these symptoms (Day, Carreon, & Stump, 2000). The literature has in fact made strong research-based arguments that proximal physical environmental characteristics of long-term care facilities significantly influence certain behaviors:

1. Camouflaged exits reduce elopement attempts (Dickinson & McLain-Kark, 1998).
2. Privacy reduces aggression and agitation and improves sleep (Morgan & Stewart, 1998).
3. Common spaces with a unique noninstitutional character are associated with reduced social withdrawal (Gotestam & Melin, 1987).
4. Walking paths with multisensory activity nodes decrease exit seeking, improve mood, and engage family members (Cohen-Mansfield & Werner, 1998).
5. Residential character is associated with reduced social withdrawal, greater independence, improved sleep, and more family visits (Minde, Haynes, & Rodenburg, 1990).
6. Sensory comprehension reduces verbal agitation (Burgio, Scilley, Hardin, Hsu, & Yancey, 1996; Cohen-Mansfield & Werner, 1997).
7. Therapeutic garden access reduces elopement attempts and improves sleep (Stewart, 1995).

8. Increased safety leads to greater independence (Sloane et al., 1991), which in turn is associated with fewer falls (Capezuti, Strumpf, Evans, Grisso, & Maislin, 1998).

Although compelling arguments are made for the therapeutic efficacy of an appropriate physical environment, until now little systematic research has been carried out to determine whether the special design features commonly found in SCUs are, in fact, effective in reducing symptoms and enhancing the quality of life for residents with dementia (U.S. Congress, 1992).

Design and Methods

Overview of Methodology

Development of an Environment–Behavior Factors Model.—Before this study, an environment–behavior (E–B) model was developed to identify the proximal physical environment factors hypothesized to influence behavioral and other health characteristics of residents with Alzheimer’s disease in nursing home SCUs. This model and its systematic development, based on the work of established researchers and theorists (Calkins, 1988; Cohen & Weisman, 1991; Hiatt, 1991; Lawton, 1990), are explained in an earlier article (Zeisel et al., 1994). A Delphi approach was used with an expert panel to test and refine the initial model and its related outcome measures. Early drafts of the model—drawn from published research findings—were distributed to panel members, each of whom was asked to rank every concept, dimension, and outcomes hypothesis on a 7-point scale indicating the degree to which particular E–B relationships represented state-of-the-art research findings. On the basis of the rankings and accompanying comments, items were deleted or combined into new concepts, and hypotheses were reformulated. Each successive draft was circulated to the group, with revised rankings returned, until there was a marked consensus improvement over earlier rankings. Those few features that continued to be ranked low by some experts and high by others in the final ranking were determined to reflect persistent state-of-research-knowledge differences in the field. These rankings were then shared with the entire expert group, and each member was asked to voice objections to the rankings, if there were any, so that these could, if possible, be resolved (Zeisel et al., 1994).

The expert panel that played such a crucial role in the model’s refinement included Margaret Calkins, PhD, IDEAS Inc.; Paul Chafetz, PhD, University of Texas; Uriel Cohen, AIA, University of Wisconsin; Betty Rose Connell, Atlanta VA Medical Center; Irving Faunce, Exeter Hospital; M. Powell Lawton, PhD, Philadelphia Geriatric Center; Nancy Mace, MA, California Pacific Medical Center; Jon Sanford, Atlanta VA Medical Center; Philip Sloane, MD, MPH, University of North Carolina at Chapel Hill;

and Myra Schiff, PhD, Canadian Alzheimer's Association.

An Alzheimer-specific set of testable E-B hypotheses resulted, describing potential effects of environmental conditions on health and behavior outcomes (Table 1). Each concept in the E-B Model includes two critical dimensions identified from published research literature and responses from the expert panel.

Two investigators independently used the concepts and dimensions in the E-B Model as a checklist to rate the physical environment of 30 SCUs during a 1-day site visit to each facility. During the rating procedure, both investigators separately rated every concept as "5 (high) to 1 (low)," generating an empirical indicator list of observed environmental features and conditions contributing to their ratings. Each feature and condition was photographed for later reference if independent ratings differed. The final set of indicators was organized into an environmental factors checklist to be quantitatively developed and used in future research to rank sites on these environmental characteristics (Table 2).

Investigators' ratings were compared. Where exact agreement was found, no further analysis was carried out. Where a difference was found, consensus was reached by referring to the photographs of the observed conditions, the rating scale, and the environmental factors checklist. In the few cases in which consensus could not be reached in this way, and where scores were 2 points apart on the 5-to-1 scale, a third rater was utilized and consensus reached. In the final version, the ratings were collapsed to a 3-point scale—representing "excellent," "moderate," and "poor" for each characteristic—because the direction of each assessment was considered more important than its degree.

Sample Site Selection.—Self-reported SCUs vary greatly in quality, and there is no official central or regional registration file of SCUs—a major problem that earlier SCU evaluation researchers have faced. Therefore, a nearly exhaustive list of 200 self-reported SCUs in New England and eastern New York was compiled through contact with Alzheimer's Association chapters in the study area. Calls were made to all 200 to determine which met the following definitional criteria:

- Functions as a self-contained unit,
- Is a physically distinct part of the building,
- Has dedicated staff to work on the unit,
- Restricts residents' movements to the physically distinct area unless monitored or accompanied by staff, and
- Includes on the unit only residents who have been diagnosed as having a dementing condition.

A letter requesting study participation was sent to the 52 sites that met the definitional criteria. Thirty SCUs agreed to participate, all of which were visited

in the process of developing the E-B checklist (Zeisel et al., 1994). A comparison of the two groups of sites—participants and nonparticipants—showed no significant differences in terms of facility size, profit and nonprofit ownership, and urban–rural location. The final 15-SCU sample was purposefully selected to maximize variability among the characteristics of the independent environmental variables as defined by the E-B checklist. By the statistical aggregation of the environmental characteristics of all sampled SCUs, clusters of independent variable conditions were created in the final hierarchical linear modeling (HLM) analysis. The purposeful sampling of the final 15 SCUs is supported by the fact that no specific SCU was treated as an independent or control case in itself.

On the basis of environmental assessments, 15 SCUs were selected that included as many of the environmental conditions as possible—high and low conditions for each of the environmental characteristics from the E-B checklist just described. For example, the few SCUs with poor exit control conditions were first expressly included in the sample to include this condition in the range of test conditions for this variable, no matter what their rating was on other conditions. The next SCU was selected to represent another uncommon environmental condition, and so on until all the conditions were filled with a balanced number of residents in each condition. Selecting facilities to ensure a full range of variation in the characteristics increases the statistical power of the analysis. A random selection approach for the final 15-SCU sample is not likely to have resulted in the extreme conditions being represented in the sample, and the analysis of significant associations would not have been possible. Obviously, the research team had no knowledge of the distribution of dependent variable conditions when the sample of residents was selected. The total number of residents in the 15-site sample was 427.

Analytic Approach.—Teresi (1994) described the problematic nature "of studies of intervention effects when institutional units (SCUs) are assigned to experimental or control conditions, but the individual is the unit of analysis ... the resulting mixed units of analysis (SCU and individual resident) can result in attenuated standard errors for the estimates of effects" (pp. S252–S253). She suggested that "special modeling techniques may be needed in these situations" (Teresi, 1994, p. S253).

HLM is such a "special" technique (Bryk & Raudenbush, 1992; Bryk, Raudenbush, Seltzer, & Congdon, 1988). In their study of correlates of quality care in long-term care facilities, Bravo, De Wals, Dubois, and Charpentier pointed out that "the simultaneous study of resident- and facility-level variables calls for a statistical approach that accounts for the nested (or hierarchical) structure of

Table 1. Alzheimer's (E-B) Factors Model

E-B Concepts	Definition or Examples	Dimensions
1. Exit control	Boundary conditions of each SCU; the surrounding walls, fences, doors, & how they are locked or otherwise limit & allow people to come and go.	<i>Unobtrusiveness</i> : the degree to which the exit doors are camouflaged by paint or other devices, the amount of hardware, & their location along side walls as opposed to the end of hallways.
2. Walking paths	Circulation space residents use for wandering & moving around.	<i>Wayfinding</i> : The presence of orienting objects along the pathway, as well as wall objects that attract residents' attention & provide them a sense of being in a place. <i>Continuosity w/destinations</i> : The absence of dead-end & cul de sac corridors, & the presence of active destinations that might encourage residents there to turn around.
3. Individual space	Spaces, primarily bedrooms, assigned to & mostly used by a limited number of residents.	<i>Privacy</i> : The number of private bedrooms in the SCU.
4. Common space	Sizes, relationships, & qualities of spaces used by all residents in the SCU.	<i>Quantity</i> : The appropriate number of common rooms for the number of residents, to avoid crowding in too few rooms & to avoid "undermanning" in too many rooms.
5. Outdoor freedom	Residents' access to common outdoor areas & the way these places support residents' needs.	<i>Availability</i> : The degree to which there is an adjacent outdoor space, & the degree of free access residents have to that place—doors unlocked & appropriate supervision.
6. Residential character	The lack of institutional surroundings, including furniture & décor, wall covering, & flooring, & layout with prominent nursing station.	<i>Supportiveness</i> : The degree to which the open space is a "therapeutic garden" with appropriate places to walk, sit, smell the plants, engage in safe & interesting activities, & be apart from others <i>Familiarity</i> : The degree to which the SCU uses residential furnishings, design features, & personal objects.
7. Autonomy support	The ways in which the facility encourages & supports residents to use their remaining faculties to carry out basic tasks & activities independently & w/dignity, including enabling staff to avoid being overprotective.	<i>Prosthetic</i> : Physical supports in the environment for residents to do things for themselves—handrails, toilet seats high enough for self-toileting, & bathtub & shower support rails.
8. Sensory comprehension	Quality of the sensory environment—acoustic, visual, thermal, odor, & kinesthetic environment in all spaces, & the degree to which these conditions may confuse residents.	<i>Meaningfulness to residents</i> : The degree to which the ambient sensory environment is familiar to residents—smells, sights, sounds, & touch—textures.

Note: E-B = environment-behavior; SCU = special care unit.

Table 2. Environment Rating Checklist Indicators

Concept	Indicators Making Up <i>high</i> Ratings
Exit control	<ul style="list-style-type: none"> Camouflaging techniques <ul style="list-style-type: none"> Location of doors along side wall of corridor (as opposed to the end of a hallway) Smaller exit signs Exit doors that resemble nonexit doors Absence of visible door hardware attracting attention Camouflage of elopement warning signal Solid, opaque doors that minimally attract resident attention (as opposed to glass doors or doors w/windows) Doors that open into a safe location, such as a garden Immediacy of controls <ul style="list-style-type: none"> Presence of window locks Locking devices that keep doors closed Degree to which elopement attempts do not require staff action Locking devices w/delayed alarms & opening
Walking paths	<ul style="list-style-type: none"> Continuous w/destinations <ul style="list-style-type: none"> Long sight lines in pathways & the absence of corners Clear destinations in corridors; absence of dead ends Presence of activity spaces at ends of path Absence of bedrooms that “trap” residents at pathway dead ends Wider hallways that allow easy 2-way walking Wayfinding <ul style="list-style-type: none"> Larger number of photos on pathway walls Biographies & resident memorabilia next to each bedroom door Presence of windows along path Frequent orienting devices along path Presence of activity spaces along path Visible landmarks & anchors along path
Individual space	<ul style="list-style-type: none"> Individual privacy <ul style="list-style-type: none"> 1-person bedrooms among the types of bedrooms Larger no. of 1-person bedrooms No residents sharing toilets Small no. of residents sharing baths or showers Presence of sink in bedroom Adequate separation between beds Bedrooms w/entrances independent of common spaces Presence of nonbedroom private away spaces Personalization opportunities <ul style="list-style-type: none"> Availability of adequate space for easy chair next to bed Encouragement of personal furniture, linens, & personal objects Amount of personalization in room Personal objects located naturally around room (not on a board) Residential-quality dividers between beds (e.g., bookshelves, not curtains on a ceiling track)
Common space	<ul style="list-style-type: none"> Uniqueness of common spaces <ul style="list-style-type: none"> Presence of kitchen, living room, dining room, & activity room Unique character of each individual common space Appropriate number of common spaces <ul style="list-style-type: none"> 3–5 common rooms Few combined multiuse spaces Adequate amount of total common space for the no. of residents
Outdoor freedom	<ul style="list-style-type: none"> Accessibility of outdoor space <ul style="list-style-type: none"> Presence of outdoor space for residents adjacent to SCU Outdoor space dedicated to SCU resident use Full access to outdoor space from inside SCU Policy & rules that support full access of outdoor space Outdoor activities that provide opportunities for garden use Appropriate plan and design of outdoor space <ul style="list-style-type: none"> Safe & appropriate garden design that supports its use Opaque, solid, nondistracting fence around garden 8-ft fence or enclosure to provide certain safety
Residential character	<ul style="list-style-type: none"> Residential size <ul style="list-style-type: none"> 7–15 SCU residents Low perceived crowding in SCU

(Table continues on next page)

Table 2. (Continued)

Concept	Indicators Making Up <i>high</i> Ratings
	Homelike character Homelike noninstitutional qualities of staff dress, décor, linens, wall accessories, furniture, & lighting
Autonomy support	Safety Ease of staff surveillance in common and private spaces Reduced risk of slipping & falling on flooring, furniture, carts, & hallway clutter Presence of proactive measures to prevent access to sharp or otherwise dangerous objects Support for independence Presence of handrails in halls and bathrooms Presence of devices that cue appropriate spatial behaviors Prosthetic supports for independent toileting, dressing, showering, & self-mobility Freedom to use outdoor space
Sensory comprehension	Staff control Staff actions that keep sensory input normal Moderate level of background noise Understandable sensory input Meaningful sensory input—activity sounds, resident sounds, activity levels, smells, lighting, colors, heat, & touch

Notes: Measurement problems prevented the “outdoor freedom” variable from inclusion in the analysis. Further research is recommended for this important environmental factor. SCU = special care unit.

the data. Hence the need for hierarchical models” (Bravo et al., 1999, p. 181). HLM was used in this study to assess the association between environmental design characteristics of SCUs (facility-level variables) and health outcomes measures of residents (individual-level variables) while taking into account quality-of-

care variables (facility-level variables) and resident characteristics (individual-level variables). Nonenvironmental variables are controlled for in the analysis by averaging the effects of the environmental variables across all groups defined by characteristics of the nonenvironmental variables.

HLM avoids inaccurate standard errors by establishing the association between an SCU characteristic and individual effects by using the sample size appropriate to their respective level of analysis. The standard errors and significance probabilities for the estimates are adjusted according to the number of data points available at each level—the different degrees of freedom associated with SCU variables versus resident variables. This avoids the attenuated standard errors that could occur if only the larger number of individuals were the unit of analysis as well as the inflated standard errors if only the smaller number of SCUs were the unit of analysis.

Using HLM analysis thus reduces the risk of making Type II—false positive—decisions about whether variables have an influence on the outcome. If only individual units of analysis were used, this would deflate the standard error of the facility-level effect, overstate its significance, and increase the risk of concluding it had a real effect when it did not (a false-positive decision). HLM was therefore used to reduce the cumulative risk of Type II errors and to more accurately estimate the actual significance of

the environmental characteristics. It was judged that alternative procedures would give less valid and more uncertain results than HLM in this situation.

Dependent Variables

Behavioral Measures.—The largest in-depth national study of SCUs and dementia residents was organized and supported by the National Institute on Aging (NIA) and began in 1991. Known as the NIA Collaborative Studies on Alzheimer’s SCUs, this 10-study coordinated project developed and validated a set of measures, known as the NIA Common Core “behavior, affect and activities measure and delirium assessment” Tool (NIA, 1993). To ensure validity and reliability, and to enable comparative analysis with the combined data from these studies, the present study incorporated scales from the NIA Collaborative Studies in the *resident profile* instrument, used to assess behavioral symptoms among study participants. Completed from medical records and professional judgment by a nurse-informant familiar with each resident, the *resident profile* includes scales from the Cohen-Mansfield Agitation Inventory (CMAI; Cohen-Mansfield, Marx, & Rosenthal, 1989), measuring aggressive, physically agitated, and verbally agitated behavior; the Multidimensional Observation Scale for Elderly Subjects (MOSES; Helmes, Csapo, & Short 1987), measuring depression and social withdrawal; and the BEHAVE-AD Psychotic Symptom List (Reisberg et al., 1987) to measure misidentification syndrome and paranoid delusions (Table 3).

For each of the 14 CMAI items, nurse-informants indicated the frequency of the following behaviors:

Table 3. Outcome Measures

Measure	Reference	No. of Items	N	\bar{x}	SD	α
CMAI (short form)	Cohen-Mansfield et al., 1989					
Physical agitation		5	426	3.63	3.94	.68
Verbal agitation		5	426	2.87	3.55	.62
Aggressive behavior		4	426	3.00	3.39	.76
MOSES	Helmes et al., 1987					
Depression		7	360	5.24	5.07	.88
Social withdrawal		6	388	10.85	4.29	.79
BEHAVE-AD	Reisberg et al., 1987					
Misidentification		4	427	0.46	1.31	.64
Paranoid delusions		4 ^a	427	1.23	2.15	.63

Note: CMAI = Cohen-Mansfield Agitation Inventory; MOSES = Multidimensional Observation Scale for Elderly Subjects; BEHAVE-AD = psychotic symptom list.

^aThis is a National Institute on Aging Common Core scale that uses three BEHAVE-AD items and one item from Cohen-Mansfield.

verbal aggression (cursing), physical aggression (hitting, kicking, biting, etc.), destroying property, self-abusive behavior, wandering, restlessness, inappropriate dress, handling items inappropriately, attention seeking, verbal repetitivism, complaining or noncompliance, making strange noises (weird laughter or crying), hiding items, and screaming. Cronbach's alpha for the three CMAI subscales was .68, .62, and .76.

For each of the 13 items from the MOSES, nurse-informants indicated for each resident the frequency of these behaviors: depression (looked or said something depressed or sad, or made sad, depressed, gloomy, or mournful sounds, but not bored ones), being worried, tense, and anxious (looked or said something worried, and cried), being pessimistic (saying the future was hopeless or unbearable), being in good spirits (happy, smiling, cheerful), and being socially withdrawn (initiating interactions, responding to social contacts, paying attention to things around the patient, keeping self-occupied, and helping other residents). Cronbach's alpha for the two MOSES subscales was .88 and .79.

For each of eight items on two BEHAVE-AD Psychotic Symptom List subscales, nurse-informants indicated per resident the frequency of paranoid delusions (being stolen from or being harmed) and misidentification syndromes (saw someone else in the mirror, saw an imposter, or saw TV actors in the room). Cronbach's alpha for the two Psychotic Symptom subscales was .64 and .63.

Controlling for Nonenvironmental Variables.—

For the physical environmental correlates of the behavioral health variables to be isolated accurately, the HLM model was used to control for potential resident-level and nonenvironmental facility-level variables—both of which were entered into the model. The first are characteristics of each resident, including cognition, activity of daily living (ADL)

skills, and length of stay in the SCU. One resident-level characteristic particularly attended to in the analysis is prescription drug use. This characteristic, if overlooked, could completely distort all findings.

The nonenvironmental facility-level characteristics controlled for in the HLM analysis include staff ratio, facility size, organization, and degree of dementia friendliness. Both sets of variables, listed in Table 4, are explained in the paragraphs that follow. There were no missing data in the HLM analysis.

Resident characteristics: Individual characteristics of the residents were considered first. Demographic information included in the analysis for each resident comprised age, sex, and length of stay. Because risk of falling and associated restraining safety measures have been associated with agitation (Capezuti, Strumpf, Evans, Grisso, & Maislin, 1998; Sloane et al., 1991), a variable specifying whether or not a resident had fallen 3 months prior to the interview date was included.

Information on residents' ability to perform ADLs as well as their cognitive status was included from data in the Minimum Data Set (MDS) that the SCUs maintained for each resident. Where no MDS data were maintained, SCU nurses generated these data for each resident in the SCU. The Activities of Daily Living scale ranges between 1 and 28 and includes such items as bed mobility, walking, dressing, eating, toileting, bathing, balance, and task segmentation. Higher values indicate greater ADL impairment. Cronbach's alpha for the 28 items in the ADL scale was .78. The MDS Cognition scale from the NIA Common Core Assessment Tool was used to determine each resident's cognitive performance. The MDS Cognition scale has 13 items relating to short- and long-term memory, and to decision-making ability. Cronbach's alpha for the 13 MDS Cognition scale items was .73

Pharmacological agents can independently affect residents' agitation, anxiety, depression, and other

Table 4. Nonenvironmental Variables Included in the HLM Model

Resident Characteristics	Prescription Drug Controls	Facility Characteristics
Age	Minor tranquilizers	Staff/resident ratio
Gender	Antidepressants	Facility size
Length of stay in facility	Other antipsychotics	Organizational status
Fell in past 3 months		Dementia friendliness
ADL skills		
Cognition		

Note: HLM = hierarchical linear modeling; ADL = activity of daily living.

behaviors. These were therefore specifically controlled for statistically. Pharmacological-therapeutic drugs were classified into three categories: minor tranquilizers (benzodiazepines, anxiolytics, sedatives, or hypnotics), antidepressants, and other antipsychotic agents. Each patient's drug record was obtained and coded according to this typology, and the patient was given a score for each type of drug taken. If any drug in each of the three categories was administered, the patient received a score of 1, and if none of this type was taken, the patient's score was 0 for that drug category.

Facility characteristics: As a way to control for the possible effects of nonenvironmental characteristics of the facilities themselves, several variables were constructed to describe each facility. The number of residents per SCU was used to take into account possible effects that facility size might have on health and behaviors (Bravo et al., 1999; Castle & Fogel, 1998; Leon & Ory, 1999). Because Castle and Fogel (1998) found that health and behaviors were influenced by organizational status, a dummy variable was created to indicate profit or nonprofit status.

A final scale, developed by rating each SCU's policy and procedures manual, was created to reflect the overall Alzheimer's appropriateness of the facility. Ratings were assigned to each SCU's policy and procedures manual on the basis of their Alzheimer specificity, and on the ratio of key dementia features (assessment, mission, staff empowerment, family support, community involvement, staff appropriateness, management or financial issues, and activities) to nondementia features (quality assurance, housekeeping or maintenance, nursing procedures, emergency procedures, research, clothing, incidents, record keeping, and physician services). Two researchers independently reviewed and ranked the documents on Likert scales. When 2 or fewer points apart, the two scores were averaged. When more than 2 points apart, a third rater mediated a discussion of the scores until consensus was reached.

Environmental characteristics: Each environmental factor, already explained in earlier paragraphs, was coded as two dummy variables: excellent environmental condition (yes or no) and poor environmental

condition (yes or no), with the medium environmental condition as the referent category.

Descriptive Statistics

Resident Characteristics.—The sample included 308 women and 119 men, ranging in age from 53 to 102 ($M = 81.14$; $SD = 7.8$). The majority (58%) were widowed, with 29% married, 6% divorced, and the remaining single or unspecified. The largest percentage (46%) of the sample was moderately to severely dependent in ADLs, with 39% experiencing mild to moderate dependency, and 15% who required supervision only or were independent. Twenty percent had cognitive impairment rated moderate to severe, 67% rated moderate, and 13% rated mild. Prescription medication use for minor tranquilizers was 37%, for antidepressants 30%, and for other antipsychotic agents 33%, with 65% of the sample on at least one psychotherapeutic prescription drug. Twenty-seven percent had experienced a fall in the past 3 months. The average length of institutionalization was 26.63 months ($SD = 20.24$), with a range of less than 1 month to 151 months for a resident 95 years old.

Facility Characteristics.—The sample included 15 facilities. The size of the facilities ranged from 20 to 50 residents ($M = 33.67$). The clinical, 24-hour staff-to-resident ratio ranged from 0.91 to 2.50 ($M = 1.54$). Nine facilities were for profit and six were not for profit (one religious and two government facilities are included). On the basis of a systematic two-person analysis of their mission statement, training protocol, policies and procedures, and activities programming, the level of Alzheimer's capability of each facility was ranked. Seven facilities were characterized as highly Alzheimer's capable, three as only Alzheimer's friendly, and five as dementia unfriendly. The intraclass correlation, expressing the variability in the outcomes from residents sampled from the same facility, was 0.36. This weak commonality of characteristics by facility is possibly due to institutional policies that exclude residents inappropriate to the care available or that provide special services benefiting a particular population.

Table 5. Bivariate Correlations Among Variables

Variable	CM Total (Prorated)	MOSES (Prorated)		CM (Prorated)			BEHAVE-AD (Prorated)
		Withdrawal	Depression	AB	PAB	VAB	
Privacy	-.254	.008	-.085	-.204	-.156	-.221	-.145
Common space	-.222	.079	.003	-.173	-.206	-.122	-.092
Exit control	-.240	.195	.149	-.125	-.230	-.180	-.122
Residential char.	-.224	.013	.025	-.202	-.109	-.205	-.085
Sensory comp.	-.208	.071	.067	-.136	-.144	-.194	-.140
Walking path	-.212	.044	.097	-.191	-.158	-.135	-.020
Mission statement	.120	-.071	-.010	.101	.073	.102	.019
Fell in the past 30 days	.034	-.091	-.100	.002	.047	.025	.012
ADL scale (28 items)	-.185	.284	.232	-.004	-.323	-.065	-.072
Length of time in institution	-.058	.065	.073	-.028	-.077	-.022	.003
No. of residents	-.242	.027	.066	-.243	-.097	-.219	-.042
Gender	-.009	-.091	-.148	-.082	-.046	.110	.041
Age	.001	-.142	-.206	-.040	-.063	.109	.046
Staff ratio	-.194	.016	-.049	-.105	-.173	-.156	-.134
Antipsychotic meds.	-.079	.217	.459	.039	-.171	-.030	.013

Notes: The figures in each cell represent the Pearson correlation between each set of variables. Boldface indicates correlations that are large enough ($r \geq .10$) and significant at $p \leq .05$. MOSES = Multidimensional Observation Scale for Elderly Subjects; AB = aggressive behavior; PAB = physically agitated behavior; VAB = verbally agitated behavior; ADL = activity of daily living; CM = Cohen-Mansfield; BEHAVE-AD = psychotic symptom list.

Facility Environmental Characteristics.—No single facility received consistent high or low scores on all its environmental characteristics. Facilities given a high rating on some characteristics received only medium scores on the remaining characteristics. Facilities scoring medium on some characteristics scored low on the remaining characteristics. Only one facility received a range of low, medium, and high scores.

Six facilities, housing 37% of the residents in the study, scored high on exit control, whereas seven scored medium (49% of the residents) and two scored low (14% of the residents). For walking paths, three facilities (18% of the residents) were high, eight facilities (50% of the residents) were medium, and four facilities, with 32% of the residents, were low. There were three facilities (16% of the residents) with excellent privacy—personalization, and six facilities each with medium and low scores with 34% and 50% of the residents, respectively. Five facilities with 27% of the residents had excellent common space, seven with 55% of the residents had medium common space, and the remaining three facilities with 18% of the residents had poor common space. Ten percent of the residents living in two facilities ranked high on residential, versus institutional, quality; the remaining eight medium-rated and five low-rated facilities each had 45% of the residents.

Five facilities with 31% of the residents scored high on autonomy support and 10 scored medium (69% of the residents). No sites scored low on autonomy support. For sensory comprehension, six facilities (36% of the residents) were high, seven facilities (46% of the residents) were medium, and

two facilities with 18% of the residents scored low. There were eight facilities (54% of the residents) with excellent scores for physical access to a garden, four facilities (27% of residents) with medium access scores, and three facilities with low access scores (19% of the residents).

Although data were collected on the physical accessibility—or absence—of gardens in each of the participating facilities, data were not systematically collected on residents’ actual access to these spaces. In other words, the data do not clearly indicate if doors to gardens were or were not kept unlocked during the day in good weather, whether staff only permitted residents to take walks when accompanied by staff, or whether residents had continual access. Because these attributes are so critical to the definition of “outdoor access,” this variable was unfortunately omitted from the analysis. Future research must gather more extensive data on this critical environmental variable to determine the impact of therapeutic gardens on behavioral health outcomes.

Results

This section reports the results of an initial bivariate analysis as well as the final multivariate analysis used to test the model that underlies this research effort. Three types of variables—resident characteristics, nonenvironmental facility characteristics, and environmental characteristics—correlate significantly with resident behavioral health measures in the bivariate analysis. The bivariate correlations of these variables with the dependent variables

Table 6. HLM Model Elements

Characteristics	Behavioral Health Measures	HLM Equations
X_1 = Privacy	Y_1 = Anxiety/aggression (Cohen-Mansfield total)	$Y_1 = 16.4 - 2.21X_1 + 0.10X_2 + 0.50X_3$
X_2 = Falling down	Y_2 = Social withdrawal (MOSES)	$Y_2 = 0.2 - 0.82X_4 + 0.10X_5 - 0.10X_6$
X_3 = ADLs	Y_3 = Depression (MOSES)	$Y_3 = 0.6 - 0.58X_7 + 0.30X_8 + 0.70X_9$
X_4 = Common space	Y_4 = All aggression (Cohen-Mansfield subscale)	$Y_4 = 11.2 - 0.23X_{10} - 0.70X_8$
X_5 = Length of stay	Y_5 = PA (Cohen-Mansfield)	$Y_5 = 6.6 - 0.40X_3$
X_6 = No. of residents	Y_6 = VA (Cohen-Mansfield)	$Y_6 = 6.5 - 0.57X_{11} - 0.10X_{12} + 0.90X_2$ $+ 2.10Y_1 + 2.10X_9 + 0.10X_{13}$
X_7 = Exit control	Y_7 = Psych. problems (BEHAVE-AD)	$Y_7 = 4.1 - 0.33X_1 - 0.11X_{12} + 0.38X_{14}$ $- 0.40X_{15}$
X_8 = Gender		
X_9 = Antipsychotic meds.		
X_{10} = Res. character		
X_{11} = Sensory comp.		
X_{12} = Staff ratio		
X_{13} = Age		
X_{14} = Walking path		
X_{15} = Mission		

Notes: HLM = hierarchical linear modeling; ADLs = activities of daily living; MOSES = Multidimensional Observation Scale for Elderly Subjects; PA = physical aggression; VA = verbal aggression; BEHAVE-AD = psychotic symptom list. Characteristics are for the environment, the resident, or the facility.

were calculated by using Pearson's correlation coefficient, in order to provide a preliminary indication of which factors were likely to be related to the outcome variables. These correlations are presented in Table 5. The environmental factors tend to be correlated with the behavioral health measures in the direction predicted, except for exit control, which, without the other variables being taken into account, was associated with increased, not decreased, withdrawal and depression. This direction is reversed in the later analysis. Several of the individual and nonenvironmental facility-level variables are also associated with the dependent variables.

The large and statistically significant correlation coefficients in the bivariate analysis do not take into account the hierarchical relationships among the variables. Therefore we consider all correlations of $r \leq .10$ to be trivial—regardless of significance, in Cohen's (1969) effect size taxonomy. Those associations that are large enough ($r \geq .10$) and significant at $p \leq .05$ are shown in boldface in Table 5.

The result of the multivariate model analysis, based on introducing potential confounders as controls, is the final test of the research model. The variables from the bivariate analysis were therefore entered in the HLM program to assess which variables remain significantly related after other factors were controlled for. The bivariate associations hold when this statistical model is used, and the exit control association is reversed once the hierarchy of variables is taken into account. A mixed HLM model was used where environmental variables were fixed, and the individual correlates were treated as

random effects. The assumption of the individual variables as random effects implies that they are assumed to vary across Level 2 variables. The individual correlates were centered on the grand mean. Our research indicates that these variables, independently—and possibly interactively—are correlated with the resident behavioral health characteristics measured in this study. Seven environmental and nine resident and nonenvironmental facility factors were entered in the final model, with one environmental variable—autonomy support—dropping out in the final HLM analysis. Table 6 presents the final variables and equations used in the HLM model. This contains the variables that remained significant after the other independent variables were controlled for. For environmental factors, 49 independent significant tests were carried out. For the resident and nonenvironmental facility factors, 63 tests were carried out. Seventeen of the relationships were statistically significant, whereas only six false positives would have been expected by chance.

In Table 7 these correlates are grouped according to the dependent behavioral health variable with which they are correlated, although in this discussion of results, the findings are presented in three sections reflecting the type of variable. Variables on the left are Level 2 variables, whereas those on the right are Level 1 variables. Findings that were significant at the .05 level were reported. In addition, five associations whose significance levels do not quite attain the conventional .05 level of significance (.051 to .068) are discussed. Their trends are all in the direction suggested by the model underlying the analysis, and they are included in this discussion as

Table 7. Environmental Correlates to Alzheimer's Symptoms: HLM Analysis Results for Levels 1 and 2

Behavioral Health		Design		Coef.	SE	T Ratio	p Value	PF Correlates	T Ratio	p Value	Variance Com.	χ^2	df
Anxiety-agg. (CM total)	Privacy-personaliz. (-)	-2.21	.73	-2.87	.019	Falling down (+) ADL performance (+)	+2.443 +3.799	.037 .005	0.002 0.004	10.6 13.5	14 14		
MOSES													
Social withdrawal	Common space variability (-)	-0.82	.40	-2.067	.068*	Length of stay (+)	+2.068	.066*	.010	12.0	8		
Depression	Exit control (-)	-0.58	.26	-2.261	.050	No. of residents (-) Gender (women +) Antipsychotic meds. (+)	-4.009 -3.568 +2.292	.004 .007 .047	— 0.380 0.050	— 7.6 20.1	— 13 12		
All aggressions (CM subscale)	Residential char. (-)	-0.23	.06	-3.896	.002	Gender (men +)	+2.151	.051*	0.460	12.6	12		
Aggression													
Physical (CM)	—					ADL performance (-) Staff ratio (-)	-3.516 -2.115	.037 .063*	0.050 —	16.4 —	14 —		
Verbal (CM)	Sensory comp. (-)	-0.57	.27	-2.156	.059*	Falling (+), Anxiety (+), Antipsych. meds. (+) Age (+)	+2.254 +2.279 +2.724 +2.323	.050 .048 .024 .045	2.070 0.890 1.060 0.001	13.0 10.1 18.4 8.11	6 6 6 5		
Psych. problems (BEHAVE-AD)	Privacy-personaliz. (-)	-0.33	.11	-2.918	.023	Mission (-)	-3.117	.018	—	—	—		
	Sensory comp. (-)	-0.11	.04	-2.668	.032								
	Walking path (+)	0.38	.15	+2.485	.042								

Notes: Findings are significant at $p < .05$. Five findings, marked by an asterisk, are in the same direction as predicted by the theoretical model but at levels that only approach conventional levels of statistical significance ($p = .051$ to $p = .068$). The varying degrees of freedom in the final column result from a different number of control variables when correlates of behavioral health are looked at. PF correlates = individual and nonenvironmental proximal factor correlates. MOSES = Multidimensional Observation Scale for Elderly Subjects; CM = Cohen-Mansfield; BEHAVE-AD = psychotic symptom list; ADL = activity of daily living; HLM = hierarchical linear modeling.

exploratory findings deserving further research. For each dependent variable, the HLM analysis first controlled for all the individual and nonenvironmental facility characteristics. Then all environmental variables were entered, with nonsignificant ones being dropped sequentially until only significant ones remained. All individual and facility variables were kept in as control variables. Only significant control variables are shown in Table 7. Model assumptions were also verified. The residuals were determined to be normally distributed, indicating that this model assumption was not violated. The remaining correlates are presented in Table 7, as well as the coefficients and their standard errors for the final fixed model, and the variance components, degrees of freedom, and chi-square values for the random effects. There was no significant evidence of heterogeneity of variance, as indicated by an *F* test for heterogeneity of variance.

E–B Influences

The HLM analysis shows that physical environmental design features correlate with behavioral health, even when individual and nonenvironmental facility characteristics are taken into account. In fact, individual and nonenvironmental facility characteristics can be seen as interacting with the following attributes of the physical environment.

The degree of privacy–personalization in the SCUs studied was negatively correlated with patient scores on the Cohen-Mansfield total aggression scale. Residents in facilities with more privacy—more rooms that are individual and more opportunities for personalization—generally scored lower on this scale, representing less anxiety and aggression.

The amount of variability among common spaces in a facility was negatively correlated with patient social withdrawal scores. The degree of social withdrawal among residents decreased as the variability among the common spaces in a facility increased. Depression was negatively correlated with another environmental factor—exit design. Residents in facilities whose exits were well camouflaged and had silent electronic locks rather than alarms tended to be less depressed. A hypothesis to explain this correlation is that residents try to elope less in such settings and that caregivers—tending to consider such environments safer—afford residents greater independence of movement. Residents who experience this greater freedom, and hence have less conflict about trying to leave the SCU, feel a greater sense of control and empowerment, leading in turn to less depression. Until further research is carried out measuring personal state-of-mind variables that might be implicated in such a process, this explanation remains only a hypothesis.

Aggression and its various expressions were also correlated with characteristics of the physical environment. Persons living in SCUs with a more

residential, less institutional environment expressed lower levels of overall aggression than those living in more institutional settings. Physical aggression, scored separately, did not appear to be associated with environmental design after individual and facility characteristics were controlled for, but verbal aggression appears to be correlated with environment. In facilities where sensory input is more understandable and where such input is more controlled, residents tended to be less verbally aggressive.

Finally, environmental design also was correlated with resident psychotic problems. Those living in environments scoring high on privacy–personalization tended to have lower scores on the psychotic problem scale. The same was true for those living in facilities with higher scores on sensory comprehension scores.

It should be noted that privacy–personalization and sensory comprehension were related to lower scores for more than one negative characteristic. In several of this study's HLM models where these two factors did not reach statistical significance, they were among the last variables dropped from the models. This suggests that privacy–personalization and sensory comprehension are likely to be particularly important environmental design features contributing to improved behavioral health outcomes.

Taken with other correlates of the behavioral health characteristics discussed in the paragraphs that follow, this analysis appears to provide evidence that environmental design is related to behavioral health outcomes among residents of SCUs with dementia-related health problems. Because the present research did not include measures of subjective control such as alienation and anomie, while it is clear that there are relationships between environment and behavioral health characteristics, we can only hypothesize what the specific links are which may relate them. Elaboration and exploration of the nature of these relationships must await future research.

Resident-Level Influences

Certain resident-level characteristics are shown through the HLM analysis to correlate with residents' behavioral health. The more a resident has problems performing ADLs, the more likely he or she is to have a lower total anxiety and aggression score on the Cohen-Mansfield scale. The likelihood of a resident falling, in contrast, was positively related to expressions of anxiety and aggression.

The longer a person has lived in a caregiving institution, the more highly correlated her or his social withdrawal score is likely to be. This may reflect the fact that those living longer in SCUs are also more likely to be confounded with progression

of dementia or other medical conditions with a developmental process.

Gender is associated with depression. Our study shows depression to be more prevalent among Alzheimer's residents who are women than among those who are men. This is also the case for those taking antipsychotic medications—the more such medications, the greater the correlation with depression, according to our findings.

In contrast, gender is correlated with overall aggression scores in the opposite direction. Male residents are more likely to score higher than female residents on overall aggression—both physical and verbal. Ability to perform ADLs is negatively correlated with all patient scores on physical aggression, whereas a patient's likelihood of falling down, level of anxiety, age, and taking of antipsychotic medications all appear to be positively correlated with the expression of verbal aggression by residents.

Nonenvironmental Facility-Level Influences

Only three nonenvironmental facility-level characteristics appear to correlate with the behavioral health measures in this study. The larger the facility—the more residents there are in the SCU—the lower the social withdrawal scores tend to be. The higher the staff ratio, the lower are the verbal aggression scores among residents. In addition, the higher the facility scores on Alzheimer capability, the fewer reported psychotic problems residents tend to exhibit.

Discussion

This research demonstrates that certain features of the physical environment in SCUs are associated with improved behavioral health among residents. The environmental features associated with both reduced aggressive and agitated behavior and fewer psychological problems include privacy and personalization in bedrooms, residential character, and an ambient environment that residents can understand. Characteristics of the environment associated with reduced depression, social withdrawal, misidentification, and hallucinations include common areas that vary in ambiance and exit doors throughout the SCU that are camouflaged.

Environments conventionally designed for the cognitively able appear to put stress on the cognitive abilities of those with Alzheimer's. One explanation for the results presented here may be that the design characteristics discussed relieve residents' cognitive stress, thus reducing their anxiety and related aggressive acts. Another is that the design features, by providing residents with greater control over their own lives, empower them and thus reduce their tendency to withdraw and even to be situationally depressed. The present research can only indicate the

direction for such interpretations. More extensive research will be required to be more definitive.

The findings support and expand on the Intervention model proposed by Beck and colleagues (1998). Each of the behavioral health characteristics measured in the present study—in addition to correlating with at least one environmental factor—was also associated with resident characteristics, such as gender, cognitive status, and medications and to nonphysical facility factors such as staff ratio and Alzheimer's friendliness of the mission. This would appear to indicate a dynamic, interactive relationship between resident characteristics and environmental features on one hand and the behavioral health of residents on the other.

For design and construction, these findings have clear implications. Even though SCU design has to meet stringent fire safety requirements and construction standards that may seem rigid and imply institutional design responses, SCUs should strive to model their interior environments after homelike settings to reduce aggressive and other symptoms. Applied in design of SCUs, these findings will lead to more private and less shared rooms, variation in common room design within an SCU, common rooms for activities located at ends of hallways, and doors located along side walls whenever possible instead of at the end of hallways where they act as "attractive nuisances." Alzheimer Association chapters are already advising consumers to take environmental design issues such as these into account when determining the quality of nursing homes, SCUs, and assisted living special care programs they are considering for their loved ones (Alzheimer's Association, 2000; Raia, Zeisel, Cacciapuoti, Stout, & Rodman, 2003).

Funding for major renovation of heavily institutional nursing home SCUs must be weighed against the potential of decreased costs for medications and increases in quality of life, not merely as cosmetic alterations.

Limitations

It is possible that the significant associations found between behavioral health characteristics and environmental factors are spurious and result from their correlation with some other unspecified or poorly specified factor. If this were the case, however, it is highly unlikely that each of the environmental factors would be significant and in the direction hypothesized.

Nevertheless, the data presented here may be limited by the questions asked and the variables studied. This presents limitations that have to be considered when the results are interpreted.

There may be *unspecified factors* not included in the model that also correlate with behavioral health characteristics. Some of these may be environmental

variables such as whether or not the SCUs had gardens that residents used, whether the environments reflected the cultural background of residents, or if they were maintained well or were cluttered and messy. In our analysis, we assumed random distribution of such characteristics, but these may have independent effects on the behavioral health characteristics measured.

One or more of the factors studied may have been only *partly specified*. For example, the study team identified two dimensions of exit control design: the degree to which the exit is camouflaged to reduce the likelihood of elopement, and the degree to which the doors were actually locked (magnetically or by key) versus unlocked but alarmed. Other dimensions of exit control that were overlooked may still be important for the analysis.

Limited variability may also be influencing the data. For example, although the research team attempted to have high and low independent variable scores for each factor, secure exits were a criterion for inclusion in the sample. One SCU with a large enough group of residents was found to have only a “black line on the floor” as its barrier to the rest of the facility, providing only one SCU in the cell representing poor exit control.

Nevertheless, the study analysis did attempt to rigorously control for resident characteristics and organizational factors that previous research has indicated might confound the data analysis. These included such resident characteristic variables as prescription drug usage, risk of falling, cognition, need for assistance with ADLs, length of stay in the facility, and age. Organizational factors included the ratio of staff to residents, the not-for-profit or for-profit status of the organization, and the dementia friendliness of the facility’s mission.

Two major limitations can only be overcome by increased research funding in this area. Resource allocation in the research led the team to a final selection of 15 sites and 427 residents, instead of 30 sites with nearly 950 residents. There is clearly a need to replicate this research with the use of more facilities as well as to gather longitudinal data to examine in greater detail the impacts of the environment on outcomes inferred by the correlations found in this study.

Future Research

This study paves the way for further exploration into environmental design as one important non-pharmacologic treatment modality for people with Alzheimer’s disease (Zeisel & Raia, 2000). Future research might focus on applying a similar methodology to other environmental factors the literature has indicated might be therapeutic. These could include accessible gardens, soothing colors, non-disorienting carpeting patterns, higher lighting levels, and alternative bathing settings.

A larger sample size in future research would increase the significance of findings and would permit the inclusion and control of a greater number of variables—environmental, individual, and facility characteristics. A more diverse sample would enable researchers to test the generalizability of the study findings to a greater variety of Alzheimer care settings—assisted living residences for people with Alzheimer’s, foster care settings, and at-home care in addition to nursing home SCUs.

An examination in future research of the cumulative effects of environmental features might also yield useful information. For example, is the association between reduced aggression and both privacy–personalization and unique common spaces cumulative, such that planning both together could augment the reduction of aggression more than either separately? Even more challenging and rewarding would be insight into the dynamic interactive and cumulative effects of environmental conditions with organizational factors as well as pharmacologic treatment.

A Significant Direction

This research demonstrates the great opportunity systematic attention to environmental factors opens for improving Alzheimer’s symptoms. The greatest likelihood for this approach to make a significant contribution is to consider environment as one of at least three modalities—pharmacologic, behavioral, and environmental—for improving the quality of life, health, and behavior of people with Alzheimer’s disease. These might well be considered three “treatments” for the disease.

As conceptual and empiric research in the area of environment and health accelerates, it is becoming increasingly clear that a combination of drug treatment, supportive environments, and focused caregiving approaches provides the highest likelihood that those with Alzheimer’s disease can indeed live more satisfying lives. The stage is set for interdisciplinary intervention studies to identify the optimum balance and arrangement of these treatment modalities.

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