

Randomized Controlled Trial of Different Models of Care for Nursing Home Residents With Dementia Complicated by Depression or Psychosis

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Objective: To compare the outcomes of 3 interventions for the management of dementia complicated by depression or psychosis: psychogeriatric case management, general practitioners with specialist psychogeriatric consultation, and standard care for nursing home residents.

Method: The sample for this 12-week randomized controlled trial consisted of 86 subjects with dementia from 11 Sydney, Australia, nursing homes, of whom 34 had depression, 33 had depression and psychosis, and 19 had psychosis. All participants received full psychiatric assessments and physical examinations. Information was obtained from the residents' families and nursing home staff. Depression measures included the Even Briefer Assessment Scale for Depression, Hamilton Rating Scale for Depression, Cornell Scale for Depression in Dementia, and Geriatric Depression Scale. Psychosis measures included the Behavioral Pathology in Alzheimer's Disease Rating Scale, Neuropsychiatric Inventory, and Scale for the Assessment of Positive Symptoms. Data were obtained from nursing home records on prescription of psychotropic medication and demographic information. Management plans were formulated by a multidisciplinary team before random assignment to interventions.

Results: All 3 groups improved from pretreatment to posttreatment on depression scales for depression groups and psychosis scales for psychosis groups. Mode of management appeared to make no difference in rate or amount of improvement; neither of the treatment group-by-time interactions were significant. Neither use of antidepressants nor use of antipsychotics predicted depression or psychosis outcomes.

Conclusion: Participation in the study was associated with improvement in depression and psychosis, perhaps because of the presence of a psychogeriatric team, the increased attention focused on residents, or the generalization of active intervention techniques to control subjects. A formula-driven psychogeriatric team case management approach was not significantly more effective than a consultative approach or standard care. This study demonstrates the difficulties and feasibility of conducting service-oriented research in nursing homes.

(*J Clin Psychiatry* 2003;64:63-72)

Received June 4, 2001; accepted May 15, 2002. From the Schools of Psychiatry and Community Medicine, University of New South Wales (Drs. Brodaty and Draper), and the Academic Department for Old Age Psychiatry, Prince of Wales Hospital, Sydney, Australia (Drs. Brodaty and Draper, Mr. Lie, and Mss. Millar, Low, Sharah, and Paton).

This study was supported by an action research grant from the National Action Plan for Dementia Care, Commonwealth Department of Health and Family Services, Commonwealth Government of Australia (Drs. Brodaty and Draper), and a special grant from the School of Psychiatry, University of New South Wales (Drs. Brodaty and Draper).

In the spirit of full disclosure and in compliance with all ACCME Essential Areas and Policies, the faculty for this CME activity were asked to complete a full disclosure statement. The information received is as follows: Mr. Lie has received honoraria from Pfizer and Janssen. Drs. Brodaty and Draper, and Mss. Low, Millar, Paton, and Sharah have no significant relationships to disclose relative to this presentation.

The authors give special thanks to the nursing home staff, residents, and families.

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Psychiatric disturbances are common in people with dementia residing in nursing homes. Rates of depression have ranged between 9% and 42%,^{1,2} and rates of psychosis, between 2.3% and 60.1%.^{2,3} These psychiatric disturbances are distressing to affected residents, are predictive of institutionalization and functional decline, cause excess disability, pose challenges to the staff caring for residents, and may be associated with behavioral disturbances.⁴⁻⁸

The treatment of this psychiatric comorbidity is difficult, and pharmacotherapy has only limited effectiveness.^{9,10} Given that the number of people in the world with dementia will almost double over the next 25 years,¹¹ the development of successful strategies for treatment of this population is urgently required. Our focus in this study was the evaluation of models of treatment for psychosis and depression in nursing home residents with dementia.

Katz et al.¹² reviewed randomized controlled trials of behavioral and psychosocial interventions in residential facilities. A program for demented residents with behav-

ioral disturbances in a Maryland nursing home, which involved resident activities, guidelines for psychotropic medication treatment, and educational rounds by a psychiatrist, resulted in significantly fewer behavioral disorders.¹³ A consultative approach to the management of depression in Part 3 homes (low level or supervised residential care facilities) in the United Kingdom had limited efficacy,¹⁴ and 3 different group interventions in a residential care setting were found to be ineffective in reducing depressive symptoms in a controlled trial.¹⁵

Could a psychogeriatric service provide an effective model of care for nursing home residents with dementia and psychiatric comorbidity? Psychogeriatric service provision to nursing homes is reportedly scant, both in Australia^{16,17} and internationally.¹⁸ Research into service provision is limited. We could find no randomized controlled trials of different models of care in nursing homes. Most studies of psychogeriatric service provision have described consultation/liaison approaches. These studies have reported improved communication, better understanding and acceptance of emotional problems by nursing staff, more accurate diagnoses, improved identification of medication side effects, increased frequency of therapeutic programs offered, and decreased hospital admissions.^{19–23}

Two uncontrolled evaluations of psychogeriatric services to nursing homes in Australia demonstrated some benefit. The first found significant improvement in the behavioral disturbances of nursing home and hostel residents treated by a community psychogeriatric team.²⁴ Although outcomes for residents with depression were not as good, 87% of referring agents and 80% of caregivers rated the service as being “helpful” or “very helpful.”²⁴ The second evaluation concerned 7 pilot Australian government-funded specialist multi-disciplinary Psychogeriatric Care Units established to assist nursing homes in better meeting the needs of older people with dementia and challenging behaviors. Significant improvements in behavioral disturbance were reported in 77% of referred residents, and 74% were rated as having an improved quality of life, while 83% of nursing homes were satisfied by the interventions (Department of Human Services and Health, National Psychogeriatric Unit Evaluation Study, available from the authors on request).

The present study compared the outcomes of a psychogeriatric team approach, a consultative general practice model, and standard care for nursing home residents with dementia complicated by depression or psychosis. Currently, psychogeriatric services to nursing homes in Australia operate mainly on a consultative model, with the implementation of management plans usually left in the hands of nursing home staff and the general practitioner (primary care physician). We hypothesized that outcome for the psychogeriatric case management model would be superior to that for the general practitioner con-

sultative model and that both would be more effective than standard care.

METHOD

Sample and Recruitment

The study was conducted in 11 nursing homes in eastern Sydney, Australia. Three of the 25 nursing homes in the area refused to participate. The remaining 22 nursing homes were stratified into small (under 60 beds), medium (60–90 beds), and large (over 90 beds), and half of the homes in each stratum were selected on the basis of geographical proximity to our center.

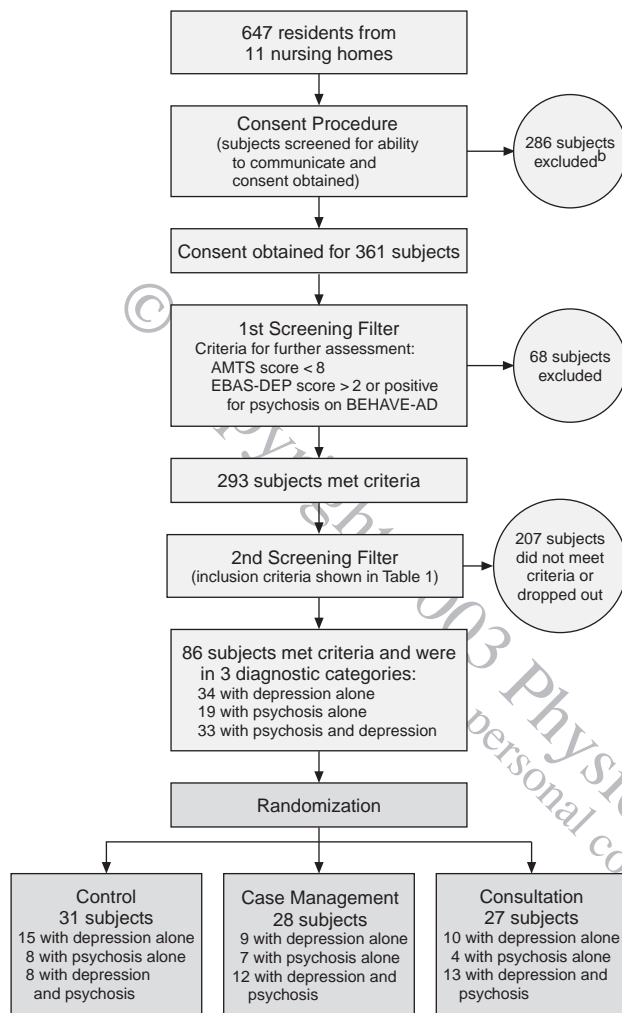
A steering committee comprised representatives of local general practitioners (primary care physicians), Alzheimer’s Association, area nursing homes, the Commonwealth Department of Health, and the research team. The directors of nursing and proprietors of the participating nursing homes gave permission for the involvement of their facility in the project. All local general practitioners (N > 500) were informed of the study. Approvals were obtained from the Ethics Committees of the South-Eastern Sydney Area Health Service and the University of New South Wales.

Consent

The study sample was selected from the entire population of 647 residents in the 11 nursing homes in a 3-stage screening strategy (Figure 1). Informed consent or proxy consent was sought for all residents. The capacity of residents to give informed consent was determined in a 2-stage process based on published guidelines.²⁵ Nursing staff initially indicated to the research team those residents whom they believed were incapable of providing consent due to aphasia, lack of English-language skills, or severity of dementia, and these 217 residents were excluded.

The research team interviewed the remaining residents to determine their capacity to give consent. Informed consent was sought from residents judged able to consent to the study. Verbal assent was obtained from residents assessed as being unable to consent but capable of participating in the study. Proxy consent was then obtained for these latter residents from their closest relative or friend (“person responsible” as defined by the Guardianship Act in New South Wales). Written information about the study was provided to the residents and their relatives. Separate consent was obtained for the interviews and participation in the trial. Residents who did not want to participate, residents whose “person responsible” did not want them to participate, and residents who were agreeable to participation but were unable to consent *and* had no “person responsible” to consent for them were excluded from face-to-face interviews. Family caregivers and general practitioners of residents consented to their participation.

Figure 1. Flow Chart Depicting Subject Selection and Randomization^a



^aAbbreviations: AMTS = Abbreviated Mental Test Score, BEHAVE-AD = Behavioral Pathology in Alzheimer's Disease Rating Scale, EBAS-DEP = Even Briefer Assessment for Depression.

^bResidents were excluded because of the following reasons: 177 were aphasic, 37 were from non-English-speaking backgrounds, 39 refused consent, 12 died before interview, 9 had no care consent, 6 had missing data, 3 were physically unwell, and 3 were transferred before interview.

No general practitioners objected to their patients commencing the study.

Screening

The first screening filter was designed to identify cases of dementia complicated by depression or psychosis in the 361 residents for whom consent had been obtained. Cognitive impairment and depression were assessed by research staff using the Abbreviated Mental Test Scale (AMTS)²⁶ and the Even Briefer Assessment for Depression (EBAS-DEP).²⁷ Nursing staff completed the Behavioral Pathology in Alzheimer's Disease Rating Scale (BEHAVE-AD).²⁸

To pass through the first screening filter, subjects had to meet the following criteria: (1) resided in the nursing home for at least 1 month (to reduce the possibility of transient situational reactions), (2) shown significant cognitive impairment indicated by a score ≤ 7 on the AMTS, and (3) manifested at least 3 depressive symptoms on the EBAS-DEP or defined psychotic symptoms on the BEHAVE-AD (Table 1).

The 293 residents who passed the first screening filter proceeded to a second, more detailed interview and assessment (Figure 1) and were rated on a number of condition-specific scales (see Table 1). To pass through this second filter, subjects had to reach predetermined cutoff criteria (see Table 1) on at least 2 depression scales or 2 psychosis scales, to minimize false-positives. The 86 residents who passed through this second filter, for whom there was agreement to participate, and who were alive at follow-up comprised the sample for this study.

Assessment

The following demographic information was obtained from case records: age; sex; length of stay in the nursing home; country of birth; fluency in English; diagnoses of dementia, depression, or any psychotic disorders; and all regular and "as required" (p.r.n.) use of psychotropic medications and their dosages.

Cognitive status was assessed using the AMTS,²⁶ a 10-item cognitive screening test administered by research staff. Scores of 7 and under indicate significant cognitive impairment.

The Resident Classification Index (RCI),³⁹ a 14-item scale designed to determine the level of Australian government funding for nursing home residents, was used to measure the general functioning and needs of subjects. Items (each rated 0–3) have 4 levels of care requirement from none or minimal to assistance on all occasions. The RCI has 4 subscales: clinical care, social and emotional support (verbal and physical disruptions, aggression), communication and sensory processes, and activities of daily living (ADL). Information was obtained from nursing home staff and nursing home records. Scores were weighted, summed, and categorized using the prescribed formula. RCI category 5 residents receive the least government assistance, and category 1 residents receive the most government assistance. The ADL subscale is highly correlated to other measures of ADL, the social and emotional support subscale is highly correlated to other measures of behavioral disturbance, and the RCI category is moderately, but significantly, correlated to cognitive impairment.⁴⁰

The Functional Assessment Staging⁴¹ was used to rate functional changes on the basis of all available information. It has 7 major stages, with a total of 16 successive stages and substages. Ratings of 6a to 6e were scored 6.0, 6.2, 6.4, 6.6, and 6.8, and ratings of 7a to 7e were similarly scored.⁴²

Table 1. Cutoff Criteria for Depression and Psychosis^a

Scale	Description	Collection Method	Cutoff Criteria
Depression			
Even Briefer Assessment Scale for Depression ²⁷	8-item depression scale validated in nursing homes ²⁹	Completed by researcher based on interview with subject	Score ≥ 3
Hamilton Rating Scale for Depression ³⁰	21-item depression scale designed for use with adults	Completed by researcher based on interview with subject and best available information	Score ≥ 16
Cornell Scale for Depression in Dementia ³¹	19-item depression scale designed for use with demented patients	Completed by researcher based on information from both subject and nursing staff	Score ≥ 10
Geriatric Depression Scale ^{32,33}	15-item depression scale designed for use with the elderly and validated in nursing homes ³⁴	Completed by researcher based on interview with subject	Score ≥ 6
Neuropsychiatric Inventory ³⁵	12-domain scale measuring psychopathology in cognitively impaired subjects	Completed by researcher based on interview with nursing staff	Depression domain frequency score ≥ 3
SAD faces (scale constructed for this study based on Faces Pain Scale ³⁶)	Visual scale; subjects asked to select which of 5 pictures of faces ranging from smiling (1) to tearful (5) best describes their mood	Completed by subject at interview with researcher	Either 4th or 5th face (tearful)
Psychosis			
Behavioral Pathology in Alzheimer's Disease Rating Scale ²⁸	26-item scale designed to measure behavioral and psychological disturbance in Alzheimer's patients	Completed by registered nursing staff	Score ≥ 1 on any paranoid and delusional ideation subscale item ^b or ≥ 2 on any hallucinations subscale item
Neuropsychiatric Inventory ³⁵	12-domain scale measuring psychopathology in cognitively impaired subjects	Completed by researcher based on interview with nursing staff	Delusions and/or hallucinations domain frequency score ≥ 3
Scale for the Assessment of Positive Symptoms ³⁷	24-item scale measuring current psychotic symptoms	Completed by researcher based on interview with subject	Score ≥ 2 on any hallucination or delusion item (Q1 to Q20)
Clinical interview	Interview to determine whether subjects are currently psychotic by DSM-IV ³⁸ criteria	Completed by the "blind" examiner and included the best available information	Positive for either hallucinations or delusions

^aPatients passed through the second screening filter by meeting cutoff criteria on 2 psychosis and/or 2 depression scales.

^bExcept for items 2 ("one's house is not one's home") and 4 ("delusion of abandonment"), as affirmation of these items was often true.

The Cumulative Illness Rating Scale⁴³ was used as a measure of physical illness burden. A cumulative score is derived from ratings of severity of impairment in each of 13 organ systems.

The measures of depression and psychosis used at screening are detailed in Table 1. The same measures were performed during reassessment after 12 weeks by a research psychologist blind to group allocation. All subjects; their families, where available; and staff involved in their care were interviewed by a senior registrar in psychogeriatrics who, using the best available information, completed DSM-IV³⁸ checklists of symptoms for depression and psychosis.

Intervention and Randomization Protocol

The 86 participating subjects were reviewed in detail at multi-disciplinary team meetings, and management plans were devised. Separate protocols were developed for residents with depression and for those with psychosis. Those who were both depressed and psychotic were primarily managed according to the depression protocol. The 2 active interventions were designed for delivery over 12 weeks. Management plans were formulated before subjects were randomly allocated (using computer-

generated numbers) to 1 of the 3 interventions: psychogeriatric case management, psychogeriatric consultation, or standard care.

Psychogeriatric case management. This intervention involved carefully defined psychological and social treatments and, where indicated, pharmacotherapy according to standard clinical procedure. These treatments were supervised by 2 geriatric psychiatrists and administered by a multi-disciplinary team, including a senior registrar in psychogeriatrics, a psychologist experienced in aged care, and a registered nurse experienced in nursing home care.

Case managers were allocated to individual residents, and treatment plans were sent to nursing homes and general practitioners at the commencement of treatment. Liaison with a resident's general practitioner occurred when pathology investigations and/or further general medical assessment were required.

Psychosocial interventions for depression (4–8 hours over 12 weeks) included the case manager providing individual supportive therapy to the resident and encouragement to participate more in pleasurable activities. Interventions for psychosis included nurse education on management of psychosis and, where possible, treatment

of sensory impairments. In both groups, residents were encouraged to participate more in general activities, families were prompted to participate in the program, and behavioral management programs were developed to address specific behavioral disturbances.

The prescriptive guidelines formulated for pharmacotherapy were as follows. Residents identified as requiring antidepressant medication were prescribed a short-acting selective serotonin reuptake inhibitor (SSRI)—either paroxetine, 20 mg/day, or sertraline, 50 mg/day, with options to increase the dose for nonresponders stepwise to 1.5 times that dose by week 4 or twice the dose by week 8. Depressed residents who were already on SSRI treatment had the dose of medication increased or were switched to an alternative SSRI in addition to psychosocial management. Residents identified as requiring antipsychotic medication, i.e., those for whom psychosis was causing distress and/or contributing to behavioral disturbance, were prescribed haloperidol. Haloperidol treatment was commenced at 0.5 mg/day and increased in 0.5-mg steps, titrated according to response and side effects to a maximum of 3 mg/day. Psychotic residents already on treatment with an antipsychotic had the dose of their medication increased.

Psychogeriatric consultation. The management plans devised at the multi-disciplinary team meeting prior to randomization were provided in writing to the nursing home staff and to the resident's general practitioner. The project team was available to provide further consultation on request from nursing staff and/or a general practitioner during the 12-week treatment phase. This style of service provision represented current practice in nursing homes with access to psychogeriatric services.

Standard care control. This group continued to receive whatever treatment they would have had were the survey not to have taken place. Revised treatment plans were sent to nursing staff and general practitioners after posttreatment phase assessment. Immediate feedback was provided if psychopathology that was a danger to the resident, e.g., suicidality, was uncovered.

Adequacy of Pharmacotherapy

The adequacy of pharmacotherapy was determined at initial assessment and at follow-up. Dosage equivalents for therapeutic efficacy of antidepressants were based on the American Psychiatric Association minimum antidepressant dosage recommendations for the treatment of major depression.⁴⁴ These were revised by the project team to cater to a geriatric population and to include antidepressants not available in the United States.⁴⁵ The dosage equivalents for therapeutic efficacy of antipsychotic medication were based on published guidelines.⁴⁶ Post hoc review of the case management groups' treatment programs was undertaken to ascertain factors contributing to treatment decisions.

Statistics

All analyses were performed using SPSS 10.0 computer software.⁴⁷ Since each subject was classified as depressed or psychotic according to different criteria (i.e., they were required to meet criteria on any 2 measures, as explained above), mean scores on each outcome measure were not considered useful in the outcome analysis. Such an approach would have been too conservative, as only a percentage of subjects met criteria on each outcome measure. Instead, for each subject, raw scores on the various measures that met criteria for depression or psychosis were converted into z scores and the highest z score was chosen as the target measure. This approach ensured that all subjects' outcome measures were set to the same scale and that outcome was measured on the scale demonstrating the highest pretreatment symptom score (or z score).

Subjects with excess missing data at either pretreatment or posttreatment (defined as greater than 20% of items on a scale missing) were excluded from repeated-measures analysis. Repeated-measures analyses of variance (ANOVAs) were performed to examine differences between treatment groups on the outcome measures from pretreatment to posttreatment. Chi-square analyses were performed to examine the difference between groups in the presence of symptoms between pretreatment and posttreatment as indicated by clinical interview. The sample sizes of 66 subjects with depression and 52 subjects with psychosis allowed 93% and 84% confidence, respectively, of detecting medium effect sizes with an alpha level of .05.

RESULTS

Attrition

Of the 102 subjects randomized into the study, 16 did not complete the study because they withdrew consent (N = 3) or they died (N = 13). There were no significant differences in gender, age, cognition, or functioning as measured by the RCI between the 86 who completed the study and the 16 who did not (gender: $\chi^2 = 0.020$, $df = 1$, $p = .888$; cognition: $t = 0.069$, $df = 2,103$; $p = .945$; age: $t = -0.033$, $df = 2,103$; $p = .926$; functioning: $t = 1.029$, $df = 2,99$; $p = .306$).

Clinical and Demographic Characteristics of the Sample

The sample consisted of 86 subjects: 34 subjects with depression alone, 19 subjects with psychosis alone, and 33 subjects with both depression and psychosis. All subjects had dementia as defined by DSM-IV criteria.³⁸ All but 1 of the subjects with depression and psychosis were included in the "depression sample," for a total of 66 subjects with depression with or without psychosis. The 1 excluded subject had both psychosis and depression prior to randomization, but was mistakenly treated only for psychosis. This subject was therefore included only in the "psychosis

Table 2. Demographic and Clinical Characteristics of the Sample^a

Variable (potential range)	N ^b	Mean (SD)	Range
AMTS total score (0–10)	86	3.29 (2.32)	1–7
Total number of medications	86	5.23 (2.79)	0–13
Total number of psychotropics	86	1.12 (0.93)	0–3
FAST score (1–7.8)	85	6.28 (1.00)	2.0–7.4
RCI weighted total score (0–104.29)	81	55.18 (22.94)	8.40–93.38
RCI category (1–5)	81	3.16 (1.05)	1–5
CIRS total score (0–56)	83	15.78 (4.40)	7–27
Duration of depressive symptoms for depression sample, mo ^c	60	32.32 (46.26)	2–276
Duration of psychotic symptoms for psychotic sample, mo ^d	45	46.38 (86.32)	0.5–456

^aAbbreviations: AMTS = Abbreviated Mental Test Score, CIRS = Cumulative Illness Rating Scale, FAST = Functional Assessment Staging, RCI = Resident Classification Index.

^bMissing data for some scales.

^cMedian depression duration = 18.

^dMedian depression duration = 14.

Table 3. Baseline Mean and Range Values, Percentage of Patients Over Cutoff for Depression or Psychosis, and ANOVA Results for Difference Between Depression Treatment Groups (N = 66) on Depression Scales and Psychosis Treatment Groups (N = 52) on Psychosis Scales^a

Scale	Mean	SD	Range	Percentage of Patients Over Cutoff (N)	F	p
Depression						
EBAS-DEP	4.92	2.27	0–8	81.8 (54) ^b	0.344	.710
HAM-D	15.58	7.01	4–33	45.5 (30)	1.080	.346
CSD	12.17	4.86	3–23	65.2 (43)	0.639	.531
GDS	8.29	3.62	1–14	72.7 (48)	0.628	.537
NPI	1.94	0.70	1–3	60.6 (40)	0.885	.420
SAD faces	3.12	1.37	1–5	30.3 (20)	0.348	.708
Psychosis						
BEHAVE-AD						
Delusions	4.02	3.11	0–13	82.7 (43)	0.230	.796
Hallucinations	2.04	2.93	0–12	34.6 (18)	0.797	.456
NPI						
Delusions	1.45	1.78	0–5	28.8 (15)	1.286	.286
Hallucinations	0.57	1.15	0–4	7.7 (4)	0.010	.990
SAPS	3.30	5.12	0–22	46.2 (24)	1.787	.179
Clinical interview	NA	NA	NA	92.3 (48)	... ^c	.740

^aAbbreviations: ANOVA = analysis of variance, BEHAVE-AD = Behavioral Pathology in Alzheimer's Disease Rating Scale, CSD = Cornell Scale for Depression in Dementia, EBAS-DEP = Even Briefer Assessment for Depression, GDS = Geriatric Depression Scale, HAM-D = Hamilton Rating Scale for Depression, NA = not applicable, NPI = Neuropsychiatric Inventory, SAPS = Scale for the Assessment of Positive Symptoms.

^bWhile all subjects were positive on the EBAS-DEP at screening, some were no longer positive when it was readministered during the assessment phase.

^c $\chi^2 = 0.602$.

sample," which comprised 52 subjects with psychosis with or without depression. The 32 subjects (37%) with depression and psychosis were included in both groups for the purpose of analysis, since their treatments were aimed at reducing both sets of symptoms. In the depression sample, 21 subjects were in the case management group, 22 subjects were in the consultation group, and 23 subjects were in the standard care group. In the psychosis

Figure 2. Change From Pretreatment to Posttreatment in Mean Z Scores for Depression Sample

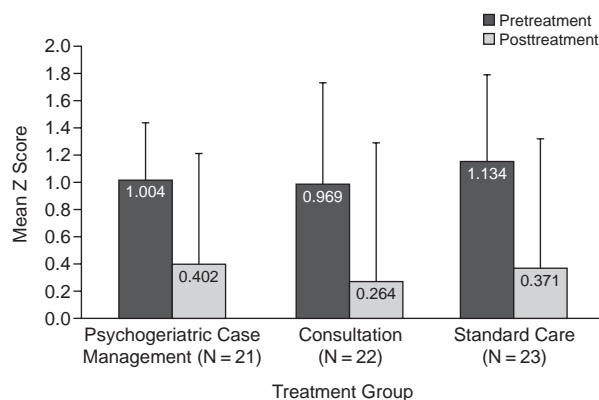
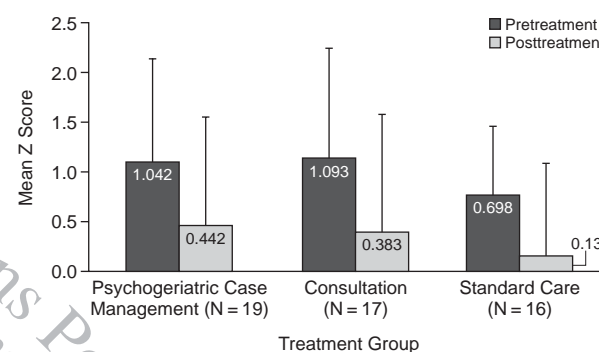


Figure 3. Change From Pretreatment to Posttreatment in Mean Z Scores for Psychosis Sample



sample, 19, 17, and 16 subjects were in each group, respectively.

Seventy-two percent of all subjects (N = 62) were female. Subjects had a mean ± SD age of 82.9 ± 8.89 years (range, 49–96 years). Their mean number of years of education was 8.65 ± 1.96 (range, 4–15). There were no significant differences in demographic data between treatment groups for either depressed or psychotic residents. Pre-intervention clinical data for the entire sample are recorded in Table 2. There were no significant differences between treatment groups for depressed or psychotic residents on pre-intervention clinical data (Table 3).

Repeated-Measures ANOVAs for Outcome Variables (z scores)

The mean z scores for each treatment group for the depressed and psychotic samples pretreatment and posttreatment are presented in Figures 2 and 3.

A significant time effect was found (F = 32.7, df = 1,61; p < .001) for the depression sample, but the

treatment group-by-time interaction was nonsignificant ($F = 0.18$, $df = 2,61$; $p = .832$). All groups showed an improvement in z scores from pretreatment to posttreatment, but there was no greater improvement in any single group. The effect size in the depression group when case management was compared with no-treatment controls was -0.185 . The effect size when case management was compared with the consultation group was -0.103 . When the case management group was compared with the other 2 groups combined, no interaction was found. This pattern of results was similar when z scores for objective or observer-rated (Hamilton Rating Scale for Depression, Cornell Scale for Depression in Dementia, Neuropsychiatric Inventory [NPI], BEHAVE-AD affective subscale) and subjective or self-reported (Geriatric Depression Scale, EBAS-DEP, SAD faces) depression scales were analyzed separately.

Z-score repeated-measures ANOVA for the psychosis sample (case management, consultation, and standard care) also revealed a significant time effect ($F = 10.7$, $df = 1,45$; $p < .01$), with all groups improving, but no group-by-time interaction ($F = 0.05$, $df = 2,45$; $p = .949$). When control and consultation groups were combined and compared with the case management group, again, no interaction was found. The effect size in the psychosis group when case management was compared with no-treatment controls was 0.065 . The effect size when case management was compared with the consultation group was 0.132 .

Chi-Square Analysis for Dichotomous Variables From the Clinical Interview

The proportion of subjects who were experiencing symptoms pretreatment and posttreatment at clinical interview was compared in the 3 treatment groups (data are missing for 4 patients in the depressed sample and 1 patient in the psychotic sample). Improvement in the depressed sample was defined as improving from a major depressive episode to a minor depressive episode or no depression, or improving from a minor depressive episode to no depression. There was no difference between the groups, with 30.0% (6/20) of case management, 23.8% (5/21) of consultation, and 47.6% (10/21) of standard care subjects improving ($\chi^2 = 2.86$, $df = 2$, $p = .240$). Improvement in the psychotic sample was defined as the absence of psychotic symptoms posttreatment when they were present pretreatment. There was no difference between the 3 groups in the proportions of residents with psychosis improving: 42.1% (8/19) in the case management, 23.5% (4/17) in the consultation, and 20.0% (3/15) in the standard care group ($\chi^2 = 2.40$, $df = 2$, $p = .302$).

Repeated-Measures ANOVAs for Behavior Outcome Measures

There was a 26.5% reduction in total NPI score in all case management subjects (depressed and psychotic resi-

dents combined), a 5.1% reduction for all consultation group subjects, and a 5.6% reduction for all standard care subjects. On the BEHAVE-AD, the case management group showed a decrease of 19.4% , the consultation group showed a 6.9% increase, and standard care subjects showed a 2.9% decrease in total score. On the behavioral disturbance domain of the BEHAVE-AD (sum of subscales C [activity disturbance] and D [aggressiveness]), the case management, consultation, and standard care groups showed 14.8% , 3.2% , and 3.6% increases, respectively.

Repeated-measures ANOVAs were performed for total NPI score, total BEHAVE-AD score, and score on the behavioral disturbance domain of the BEHAVE-AD. No time effects (NPI: $F = 2.582$, $df = 1,83$; $p = .112$; BEHAVE-AD total: $F = 0.453$, $df = 1,84$; $p = .503$; BEHAVE-AD behavioral disturbance: $F = 0.563$, $df = 1,84$; $p = .455$) or group-by-time effects (NPI: $F = 0.678$, $df = 2,82$; $p = .510$; BEHAVE-AD total: $F = 0.846$, $df = 2,83$; $p = .433$; BEHAVE-AD behavioral disturbance: $F = 0.149$, $df = 2,83$; $p = .862$) were found. A comparison of the case management group with the combined consultation and standard care subjects in a 2×2 analysis also failed to identify a time effect (NPI: $F = 3.665$, $df = 1,84$; $p = .059$; BEHAVE-AD: $F = 1.137$, $df = 1,83$; $p = .289$) or interaction effect (NPI: $F = 1.3623$, $df = 1,83$; $p = .247$; BEHAVE-AD: $F = 1.486$, $df = 1,84$; $p = .226$).

Adequacy of Pharmacotherapy

At initial assessment, 36.3% (24/65) of the depression sample were receiving adequate antidepressant therapy, 15.2% (10/65) were on antidepressant treatment at an inadequate dose, and 47.0% (31/65) were not on treatment with antidepressants (antidepressant data missing for 1 subject in the standard care group). There was no significant difference between treatment groups on adequacy of pre-intervention antidepressant use ($\chi^2 = 4.37$, $df = 4$, $p = .359$).

We reviewed the adequacy of pharmacotherapy given to those subjects during the intervention period in the case management group compared with the other 2 groups. For the depression group, 38.1% of case management subjects (8/21), 36.4% of consultation subjects (8/22), and 4.5% of standard care subjects (1/22) were assessed to be on adequate medication treatment by the end of the study (data missing for 1 subject). Chi-square analysis indicated a significant difference between groups ($\chi^2 = 8.057$, $df = 1$, $p = .018$). Thirteen subjects in the case management group were found to be on inadequate medication treatment at the end of the study. Of these, 5 subjects had been treated with recommended psychosocial interventions, 4 subjects had medical problems that affected medication use, 2 subjects had developed significant medication adverse effects and antidepressants had been discontinued, 1

subject refused medication (but was agreeable to psychosocial treatment), and 1 subject was on "possibly" adequate treatment. Of the 7 patients treated with psychosocial treatments (including 2 unable to tolerate medication due to medical problems), 2 recovered.

For the psychosis sample, 21.1% of case management subjects (4/19), 11.8% of consultation subjects (2/17), and 0.0% of standard care subjects (0/16) were assessed to be on adequate medication treatment by the end of the study. Chi-square analysis indicated no significant differences between groups ($\chi^2 = 2.655$, $df = 1$, $p = .103$), although these chi-square analyses must be interpreted with caution due to small cell sizes. Seventeen subjects in the case management group were found to be on inadequate medication treatment at the end of the study: 6 were on treatment with low-dose antipsychotics, with 3 of these being restricted by adverse effects; 2 subjects refused medication; and 1 had an adequate dose of antipsychotic discontinued by the specialist team before the end of the study due to the patient's improvement. Five subjects were treated with psychosocial interventions (3 of whom improved), and 3 had medical problems.

Post Hoc Analyses

There was no relationship between change in highest z score and duration of symptoms prior to study entry (Pearson's $R = 0.098$, $p = .464$; Pearson's $R = -0.135$, $p = .380$ for depression and psychosis, respectively). Nor was there any relationship between adequacy of pharmacotherapy, irrespective of group allocation, and outcome ($F = 1.515$, $df = 2,61$; $p = .228$; $F = 0.021$, $df = 2,45$; $p = .980$ for depression and psychosis, respectively). Finally, we performed an analysis of the raw data that restricted the sample to subjects who were positive on the Cornell Scale for Depression in Dementia for depressed residents and the BEHAVE-AD psychosis subscale for residents with psychosis. Once again, we found no time-by-group interaction.

The power to detect differences between nursing homes on improvement was low. Although there appeared to be differences between nursing homes on improvement in depression, these did not reach statistical significance ($F = 1.739$, $df = 1,10$; $p = .096$). The difference between nursing homes on improvement in psychosis was nonsignificant ($F = 0.698$, $df = 1,10$; $p = .728$).

DISCUSSION

Despite a relatively brief follow-up period of 12 weeks, nursing home residents with dementia complicated by depression and/or psychosis improved regardless of intervention. This improvement could reflect either (1) the natural history of the disorder or (2) a nonspecific intervention effect across groups. The natural history of episodes of depression, persecutory ideas, and hallucina-

tions in Alzheimer's disease is that they last about 16 to 19 months.⁴⁸ The median duration of symptoms prior to the study was 18 months for depression and 14 months for psychosis. We found no relationship between duration of symptoms prior to intervention and outcome for the sample as a whole or for individual groups.

There may have been "leakage" of treatment techniques from resident to resident. For example, stimulation activities designed for a depressed resident in the case management intervention group may have prompted nurses to use the same approaches for residents in other groups. The mere presence of a specialist mental health team within the nursing home for approximately 6 months may have inadvertently supported staff in the care of all residents. However, no additional specialist intervention was delivered to consultation and control groups, even though requests for such treatment were allowed. We considered randomizing nursing homes in order to overcome these difficulties and to enable more staff education, but were concerned that differences in practice between homes would have been a greater confound. Finally, the assessment procedure may have produced a Hawthorne effect, militating against finding a difference between groups.

Previous intervention studies in nursing homes have had mixed results. Ames¹⁴ failed to demonstrate any benefit in the psychogeriatric treatment of depression in Part 3 home residents in London, England. In their review of evidence-based nursing home care for patients with dementia, Katz and colleagues¹² found that while there have been many interventions aimed at reducing psychotropic use and use of restraints, few randomized studies have attempted to change behavior. Rovner and colleagues¹³ demonstrated positive behavioral outcomes in traditional units. The only randomized trial to date in special care units showed modest but significant effects on engagement, sociability, and positive affect.⁴⁹ Katz and colleagues¹² concluded that augmented activities together with staff education and guidelines for the use of psychoactive medications can decrease behavioral and psychological symptoms in nursing home residents with dementia.

There were trends toward greater improvement in behavioral disturbance in the case management group, and the effect sizes of the interventions were positive. We did not have sufficient power to determine the significance of these small effect sizes. Several other explanations are possible for the failure of the case management intervention to have a superior effect. The "dose" of pharmacologic and psychosocial intervention may have been insufficient. Many subjects did not receive recognized adequate doses of appropriate medication, although the reasons for this were clinically sound. Nevertheless, in depressed subjects, a higher proportion of those in the case management group were receiving adequate doses. In any case, we failed to demonstrate a drug dose effect; (the study was not powered to examine this). The intensity of

psychosocial interventions could have been greater had we had more staff to assist, but the availability of staff in this study more accurately reflects the real world, where there are rarely sufficient staff to undertake intensive behavioral or other programs. In retrospect, it may have been advantageous to involve residents' families more. It is also possible that the intensive half-day diagnostic assessment that each subject received may have attenuated the difference between models by inadvertently having a therapeutic effect.

Most trials of treatment for depression and psychosis in nursing homes have focused on drug treatments. Perhaps too much has been expected of the drug treatments. Nortriptyline has been shown to have some efficacy, and sertraline, to have no benefit over placebo in treating depressed late-stage Alzheimer's patients in nursing homes.^{50,51} Outside of nursing homes, Reifler and colleagues,⁵² in their seminal study, found no effect for imipramine for depression in patients with dementia, but significant benefits for moclobemide and citalopram have been demonstrated.^{53,54}

As regards psychosis, haloperidol, risperidone, and olanzapine have been reported to be significantly more efficacious than placebo in treating psychotic symptoms in institutionalized Alzheimer's disease subjects.⁵⁵⁻⁵⁸ In their meta-analysis, Schneider et al.⁹ found that traditional antipsychotics were only 18% more effective than placebo in the treatment of agitation. Novel antipsychotics may hold more promise than the traditional haloperidol used in this study, but were unavailable in Australia as subsidized medications.

We rejected noncompliance with medications as an explanation as they were given by nursing staff. Nor were intercurrent treatments a confound, as we found no evidence of psychotropic prescribing beyond our trial medications.

One limitation to the study is that subjects were selected according to preset criteria rather than by referral of those whom staff or family recognized as requiring help. Future studies would benefit from a more naturalistic design, randomizing only those residents referred to a specialist service. Second, our use of multiple entry criteria, which were designed to detect the different forms or presentations of depression and psychosis, may have been too complex. Future studies may benefit from a simpler approach of using just 1 rating scale for each condition. The validity of the rating instruments in residents with moderate-to-severe dementia is a separate question we are currently examining. Third, we had low power to detect small effect sizes.

In this study, we found that participating nursing home residents with depression and psychosis improved significantly with time, but that this study's model of specialist mental health care provided directly or through consultative advice had no appreciable benefit over that evident in a control group. This study demonstrates the feasibility

of conducting health services research in a nursing home setting, but also underscores the difficulties. In comparison to pharmacologic research, health services research is badly needed, but is underfunded and underresourced (our study received approximately US \$140,000 in 1996), particularly as it is time-consuming and labor-intensive. Future studies may tailor recommendations to the individual, an approach we tried to adopt, albeit within a formulaic framework; lengthen the follow-up period; and, as with drug evaluation studies, be undertaken across multiple sites. Studies may also focus on identifying those patients who improve and those who do not, to better target individuals in whom more intensive interventions may be warranted.

Drug names: citalopram (Celexa), haloperidol (Haldol and others), imipramine (Tofranil, Surmontil), nortriptyline (Pamelor, Aventyl, and others), olanzapine (Zyprexa), paroxetine (Paxil), risperidone (Risperdal), sertraline (Zoloft).

Disclosure of off-label usage: The authors have determined that, to the best of their knowledge, no investigational information about pharmaceutical agents has been presented in this article that is outside U.S. Food and Drug Administration–approved labeling.

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