Clinical Effectiveness of Integrating Depression Care Management Into Medicare Home Health
The Depression CAREPATH Randomized Trial

Martha L. Bruce, PhD, MPH; Patrick J. Raue, PhD; Catherine F. Reilly, MPH; Rebecca L. Greenberg, MS; Barnett S. Meyers, MD; Samprit Banerjee, PhD; Yolonda R. Pickett, MD, MS; Thomas F. Sheeran, PhD, ME; Angela Ghresquiere, PhD; Diane M. Zukowski, RN, BSN; Vianca H. Rosas, MPH; Jeanne McLaughlin, MSN, MSEd; Lori Pledger, RN-BC; Joan Doyle, RN, MSN, MBA; Pamela Joachim, RN, MA; Andrew C. Leon, PhD

IMPORTANCE Among older home health care patients, depression is highly prevalent, is often inadequately treated, and contributes to hospitalization and other poor outcomes. Feasible and effective interventions are needed to reduce this burden of depression.

OBJECTIVE To determine whether, among older Medicare Home Health recipients who screen positive for depression, patients of nurses receiving randomization to an intervention have greater improvement in depressive symptoms during 1 year than patients receiving enhanced usual care.

DESIGN, SETTING, AND PARTICIPANTS This cluster randomized effectiveness trial conducted at 6 home health care agencies nationwide assigned nurse teams to an intervention (12 teams) or to enhanced usual care (9 teams). Between January 13, 2009, and December 6, 2012, Medicare Home Health patients 65 years and older who screened positive for depression on routine nursing assessments were recruited, underwent assessment, and were followed up at 3, 6, and 12 months by research staff blinded to intervention status. Patients were interviewed at home and by telephone. Of 502 eligible patients, 306 enrolled in the study.

INTERVENTIONS The Depression Care for Patients at Home (Depression CAREPATH) trial requires nurses to manage depression at routine home visits by weekly symptom assessment, medication management, care coordination, education, and goal setting. Nurses’ training totaled 7 hours (4 onsite and 3 via the web). Researchers telephoned intervention team supervisors every other week.

MAIN OUTCOMES AND MEASURES Depression severity, assessed by the 24-item Hamilton Scale for Depression (HAM-D).

RESULTS The 306 participants were predominantly female (69.6%), were racially/ethnically diverse (18.0% black and 16.0% Hispanic), and had a mean (SD) age of 76.5 (8.0) years. In the full sample, the intervention had no effect ($P = .13$ for intervention × time interaction). Adjusted HAM-D scores (Depression CAREPATH vs control) did not differ at 3 months (10.5 vs 11.4, $P = .26$) or at 6 months (9.3 vs 10.5, $P = .12$) but reached significance at 12 months (8.7 vs 10.6, $P = .05$). In the subsample with mild depression (HAM-D score, <10), the intervention had no effect ($P = .90$), and HAM-D scores did not differ at any follow-up points. Among 208 participants with a HAM-D score of 10 or higher, the Depression CAREPATH demonstrated effectiveness ($P = .02$), with lower HAM-D scores at 3 months (14.1 vs 16.1, $P = .04$), at 6 months (12.0 vs 14.7, $P = .02$), and at 12 months (11.8 vs 15.7, $P = .005$).

CONCLUSION AND RELEVANCE Home health care nurses can effectively integrate depression care management into routine practice. However, the clinical benefit seems to be limited to patients with moderate to severe depression.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01979302

Published online November 10, 2014.
Clinically significant depression affects more than 25% of older patients receiving home health care, twice the rate of those receiving primary care. This high prevalence is consistent with the disability, medical morbidity, and psychosocial stressors characterizing these patients. Depression is persistent and associated with suicidal ideation, falls, and hospitalization in home health care patients, a population already at risk for adverse outcomes.

This article reports the results of a cluster-based randomized effectiveness trial targeting depressive symptoms in Medicare Home Health patients. Medicare recommends depression screening and intervention for home health care patients, but interventions are needed that are clinically effective and feasible. The structure and practice of home health care pose challenges to this goal. First, more than 97% of patients are referred for medical or surgical conditions and have multiple comorbidities. Depression care must fit within many other clinical demands. Second, Medicare funds mental health services for home health care patients with primary psychiatric diagnoses; however, the availability of specialized clinicians is inadequate, and most agencies do not have psychiatric programs. Third, Medicare reimburses agencies for skilled nursing by payment based on existing skills and use of terms and concepts consistent with primary care physicians in treating and managing patients over time.

The Depression Care for Patients at Home (Depression CAREPATH) trial was developed collaboratively by researchers, home health care clinicians, and administrators seeking a clinically effective intervention that could be easily integrated into routine practice. The intervention adapted key functions of collaborative depression care, an evidenced-based approach to primary care. The cornerstone of collaborative care is managing depression as a chronic illness, coupling guideline-based treatment (eg, pharmacological therapy or psychotherapy) with care management. The depression care manager role was created to support primary care physicians in treating and managing patients over time.

The major innovation of the Depression CAREPATH relative to the primary care model is that, rather than assigning depression care management (DCM) to a unique individual, every home health care nurse is trained to manage depression as part of routine visits and discharge planning. The training builds on existing skills and uses terms and concepts consistent with home health care practice.

This study used clinically informed research measures to determine an intervention’s effectiveness in reducing depression severity in medical home health care patients with clinically significant depression. The primary hypothesis was that, among patients who screen positive for depression on routine nursing assessments, patients receiving care from nurses randomized to the Depression CAREPATH intervention would have greater reduction in depressive symptoms at 3, 6, and 12 months than patients receiving enhanced usual care. Because the protocol included further evaluation of patients who screened positive for depression to identify patients needing active DCM, secondary analyses were stratified by depression severity. With an eye toward feasibility and sustainability, the effectiveness of the intervention was tested at 6 heterogeneous community-based home health care agencies nationwide with minimal research support.

Methods

Design, Setting, and Patients

The trial was approved by the institutional review boards of Weill Cornell Medical College, Montefiore Health System, and the University of Pennsylvania Health System. Written informed consent was obtained from study participants. The trial used a cluster randomized design (Figure 1). At 6 certified home health care agencies, preexisting nurse teams were randomized to an intervention or to enhanced usual care. Medicare Home Health patients 65 years and older who screened positive for depression on routine nursing assessments were recruited and received structured clinical research interviews for depression severity, with follow-up assessments at 3, 6, and 12 months. Patients were recruited between January 13, 2009, and December 6, 2012.

Agencies

Agencies in the following 6 locations were selected for regional heterogeneity: (1) Little Rock and rural Arkansas; (2) Miami–Dade County, Florida; (3) suburban Detroit, Michigan; (4) Bronx, New York; (5) greater Philadelphia, Pennsylvania; and (6) rural and small-town Vermont and New Hampshire. Initially planning to use 5 agencies, we added 1 to increase the number of nurse teams.

Nurse Teams

The unit of randomization was the nurse team, defined by preexisting groups of nurses and supervisors. Agencies were required to enroll at least 2 teams in the study. Within agencies, the statistician (A.C.L.) randomized teams in equal proportions to the intervention or to enhanced usual care; randomization of unevenly numbered teams favored the intervention, resulting in 12 intervention teams and 9 comparison teams. The mean (SD) team size was 8.5 (3.4) nurses, with no difference in the mean team size between the intervention and enhanced usual care (8.3 vs 8.7, P = .85).

Patients

Agencies used Medicare’s mandatory Outcome and Assessment Information Set (OASIS) to identify Medicare patients 65 years and older who screened positive on the 2-item depression screen and met other research eligibility criteria, including no dementia, life expectancy exceeding 6 months, no active suicidality, English or Spanish speaking, and no significant hearing or speech impairment. During 1 year, agency personnel telephoned up to 4 eligible patients per week to introduce the study. With patients’ agreement, local research assistants (RAs) visited them at home, confirmed their eligibility, and obtained signed consent.

Local RAs, who were trained and supervised by Weill Cornell Medical College investigators (P.J.R., C.F.R., and T.F.S.), conducted in-person interviews and then assigned a Weill Cornell Medical College RA, who telephoned within 2 days. Weill
Cornell Medical College RAs, referencing the in-person assessment, conducted telephone assessments at baseline and at 3, 6, and 12 months of follow-up. Patients who missed interviews remained eligible for subsequent assessments. In some cases, RAs recorded information from family members. Local and Weill Cornell Medical College RAs were blinded to participants’ intervention status. When detecting active suicidal risk, RAs followed structured protocols and consulted study clinicians (P.J.R. and B.S.M.), who in 29 instances contacted participants’ physicians or emergency medical services.

**Intervention Groups**

The Depression CAREPATH intervention includes a clinical protocol and infrastructural support. The intervention and its development are described in detail elsewhere and briefly below.

Researchers (M.L.B., P.J.R., C.F.R., R.L.G., and T.F.S.) helped agencies develop suicidal risk protocols, determine referral procedures, and integrate the protocol into their electronic clinical management system. The clinical protocol was designed for patients who screened positive on the OASIS clinician protocol was designed for patients who screened positive on the OASIS
2-item depression screen, now the Patient Health Questionnaire (PHQ-2).\(^{26}\) Positive screens were defined as a PHQ-2 score of 3 or higher or a comparable score on the preceding OASIS.

The first step of the protocol was to assess depression severity using the 9-item PHQ (PHQ-9), a brief questionnaire used widely in medical settings.\(^{27}\) For patients with a PHQ-9 score of 10 or higher, nurses followed DCM guidelines during routine visits on a weekly basis (or at each visit if seen less frequently). Depression care management required no additional home visits. Clinical functions were (1) to assess depressive symptoms weekly using the PHQ-9, (2) to coordinate care with physicians or specialists as clinically indicated (eg, worsening symptoms or no improvement), (3) to manage adverse effects and adherence to antidepressant medications, (4) to educate patients and families, and (5) to assist patients with feasible short-term goals (eg, grooming and socializing). Nurses were expected to monitor symptoms of patients with lower PHQ-9 scores.

Researchers (P.J.R., C.F.R., Y.R.P., and T.F.S.) provided separate 4-hour in-person training on depression assessment and DCM, each followed 1 month later by a 3-hour web booster. Nurses were not informed when patients enrolled in the study and were expected to follow the Depression CAREPATH protocol regardless of patients’ research participation. Researchers remained in contact with intervention teams through 30-minute telephone conferences with intervention team supervisors every other week.

**Enhanced Usual Care**

Nurses had full access to resources generated during infrastructural development. They participated in depression assessment training. They did not receive DCM training and were expected to follow agencies’ standard procedures for depression. Intervention team supervisors were not offered telephone support.

**Outcomes and Covariates**

**Outcomes**

Depression severity was measured at all assessments using the 24-item Hamilton Scale for Depression (HAM-D).\(^{28}\) a clinically informed, structured interview administered reliably by telephone.\(^{29,30}\) The study psychiatrist (B.S.M.), psychologist (P.J.R.), and principal investigator (M.L.B.) reviewed all information from each interview to determine consensus HAM-D scores. The HAM-D interrater reliability among Weill Cornell Medical College RAs was 0.92, based on 34 independently rated interviews. Consistent with prior research, clinically significant depression was defined as a HAM-D score of 10 or higher.\(^{25,31-33}\)

**Covariates**

Sociodemographics included age, sex, self-reported race/ethnicity, marital status, and education, as well as whether an individual was living alone and whether his or her income was below the poverty level. Disability was determined by limitations in activities of daily living (ADLs) and instrumental ADLs (IADLs).\(^{34}\) Medical burden was assessed using the Chronic Disease Scale.\(^{37}\) A depression diagnosis was based on the Structured Clinical Interview for Axis I DSM-IV Disorders,\(^{39}\) reviewed during HAM-D consensus conferences to determine the presence of major or minor depressive disorder (MMD). Depression treatment included antidepressants and psychotherapy. Cognitive status was determined using the Mini-Mental State Examination.\(^{39}\)

**Sample Size and Statistical Analysis**

**Sample Size**

In planning, power was simulated in a 3-level hierarchical linear mixed-effects model (patients nested within nurse, nurse within team, and team within agency). A sample size of 500 (5 × 4 × 5 × 5) and 15% attrition were assumed. Two intraclass correlation coefficients reflecting variations in patient within nurse and nurse within team were modeled and assumed equal (0.05 for both). Based on 2-sided α = .05, the study had 92% power to detect a 0.5 standardized difference (Cohen 𝑑) or a HAM-D score change of 3.45 points from baseline. The final sample was smaller than anticipated because of an unexpectedly high exclusion rate but was sufficiently large to detect clinically substantial effects owing to the low observed intraclass correlation coefficient.

**Descriptive Statistics**

All covariates were tested for group differences using χ² test or generalized Fisher test (as appropriate) for categorical variables. t Test or Wilcoxon rank sum test (as appropriate) was used for continuous variables.

**Longitudinal Analysis of the HAM-D**

The primary analysis of HAM-D score change from baseline involved all participants (N = 306) in a longitudinal mixed-effects model with intervention, time trend parameters, and intervention × time interaction as fixed effects and a participant-level random intercept using statistical software (SAS 9.3; SAS Institute Inc). Secondary analyses first estimated a longitudinal model of the full sample with baseline depression severity (BDS) (defined by a score of <10 vs ≥10 on the HAM-D) as intervention moderator and then stratified by BDS. The moderator analysis added fixed effects for moderator, moderator × intervention interaction, moderator × time interaction, moderator × time squared interaction, and moderator × intervention × time interaction. A random intercept for patients clustered within nurse team resulted in a zero intraclass correlation coefficient; hence, nurse team cluster effect was adjusted as a fixed covariate. Post hoc tests for intervention difference at different time points were adjusted for multiple comparisons using the step-down procedure by Holm\(^{40}\) that controls familywise error rate. Effect size (Cohen 𝑑) for intervention difference was based on the mixed-effects model estimated least squares means (SDs) (raw) at 3, 6, and 12 months.

**Results**

**Participant Flow**

Using OASIS data, 755 patients screened positive for depression and met other eligibility criteria. Of these, 253 were no lon-
ger eligible when contacted because of hospitalization (n = 128), medical severity (n = 45), hearing or speech impairment (n = 61), or death (n = 19). Of 502 remaining eligible patients, 337 consented, 131 refused, and 34 could not be contacted. The consented did not differ by study group but varied by OASIS-recorded race/ethnicity (60.5% white, 100.0% Hispanic, and 77.3% black; \( P < .001 \)) and decreased with age (\( P = .007 \)). At the home interview, 306 of 337 consented patients met full eligibility criteria, 30 were determined ineligible (24 for dementia), and 1 withdrew.

**Participant Characteristics**

Participant age ranged from 65 to 98 years, 18.0% were black, 16.0% were Hispanic, and 39.5% had income below the poverty level (Table 1). Participants reported substantial disability and medical burden. Half (51.3%) were taking antidepressants, and 68.0% had MMDD. Compared with enhanced usual care patients, intervention patients had greater IADL disability and were less likely to live alone or have MMDD.

The sample’s distribution of primary diagnoses (submitted to Medicare) was similar to national statistics, differing only by more circulatory system disease and injury and poisoning and fewer skin and subcutaneous tissue conditions (Table 2). Primary diagnoses did not differ by study group.

The mean (SD) depression severity (on the HAM-D) was 14.2 (7.8) (range, 0-39). Most (68.0%) scored at least 10 on the HAM-D, with no significant difference between study groups. Compared with less depressed participants, those with a HAM-D score of 10 or higher were younger (75.6 vs 78.3 years, \( P = .005 \)), more disabled (1.54 vs 1.13 ADLs, \( P = .03 \)), and more likely to be taking antidepressants (55.3% vs 41.8%, \( P = .03 \)). Among those with a HAM-D score of 10 or higher, interven-

### Table 1. Baseline Characteristics of Study Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Full Sample (N = 306)</th>
<th>Depression CAREPATH (n = 185)</th>
<th>Enhanced Usual Care (n = 121)</th>
<th>( P ) Value for Statistical Test of Group Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) [range]</td>
<td>76.5 (8.0) [65-98]</td>
<td>76.1 (7.9)</td>
<td>77.1 (8.2)</td>
<td>.32</td>
</tr>
<tr>
<td>Female sex, No. (%)</td>
<td>213 (69.6)</td>
<td>126 (68.1)</td>
<td>87 (71.9)</td>
<td>.48</td>
</tr>
<tr>
<td>Education, mean (SD) [range], y</td>
<td>12.0 (3.5) [3-22]</td>
<td>11.9 (3.5)</td>
<td>12.0 (3.4)</td>
<td>.93</td>
</tr>
<tr>
<td>Race, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>247 (80.7)</td>
<td>147 (79.5)</td>
<td>100 (82.6)</td>
<td>.49&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Black</td>
<td>55 (18.0)</td>
<td>36 (19.5)</td>
<td>19 (15.7)</td>
<td></td>
</tr>
<tr>
<td>Other&lt;sup&gt;c&lt;/sup&gt;</td>
<td>4 (1.3)</td>
<td>2 (1.1)</td>
<td>2 (1.7)</td>
<td></td>
</tr>
<tr>
<td>Hispanic ethnicity, No. (%)</td>
<td>49 (16.0)</td>
<td>33 (17.8)</td>
<td>16 (13.2)</td>
<td>.28</td>
</tr>
<tr>
<td>Marital status, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>93 (30.4)</td>
<td>58 (31.4)</td>
<td>35 (28.9)</td>
<td>.43</td>
</tr>
<tr>
<td>Widowed</td>
<td>127 (41.5)</td>
<td>80 (43.2)</td>
<td>47 (38.8)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>86 (28.1)</td>
<td>47 (25.4)</td>
<td>39 (32.2)</td>
<td></td>
</tr>
<tr>
<td>Living alone, No./total No. (%)</td>
<td>142/304 (46.7)</td>
<td>77/183 (42.1)</td>
<td>65/121 (53.7)</td>
<td>.05</td>
</tr>
<tr>
<td>Income below the poverty level, No./total No. (%)&lt;sup&gt;d&lt;/sup&gt;</td>
<td>83/210 (39.5)</td>
<td>47/124 (37.9)</td>
<td>36/86 (41.9)</td>
<td>.56</td>
</tr>
<tr>
<td>Source of referral to home health care, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient</td>
<td>44 (14.4)</td>
<td>26 (14.1)</td>
<td>18 (14.9)</td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>165 (53.9)</td>
<td>97 (52.4)</td>
<td>68 (56.2)</td>
<td>.70</td>
</tr>
<tr>
<td>Rehabilitation or SNF&lt;sup&gt;e&lt;/sup&gt;</td>
<td>97 (31.7)</td>
<td>62 (33.5)</td>
<td>35 (28.9)</td>
<td></td>
</tr>
<tr>
<td>No. of limitations, mean (SD) [range]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADL</td>
<td>1.4 (1.6) [0-6]</td>
<td>1.5 (1.7)</td>
<td>1.2 (1.4)</td>
<td>.10</td>
</tr>
<tr>
<td>IADL</td>
<td>3.3 (1.6) [0-6]</td>
<td>3.5 (1.5)</td>
<td>3.1 (1.7)</td>
<td>.03</td>
</tr>
<tr>
<td>No. of reported medical conditions, mean (SD) [range]</td>
<td>6.1 (2.5) [1-15]</td>
<td>6.1 (2.5)</td>
<td>6.0 (2.5)</td>
<td>.54</td>
</tr>
<tr>
<td>No. of prescription medications, mean (SD) [range]</td>
<td>9.0 (4.0) [0-22]</td>
<td>9.3 (3.8)</td>
<td>8.6 (4.2)</td>
<td>.11</td>
</tr>
<tr>
<td>CDS score, mean (SD) [range]</td>
<td>6.0 (3.0) [0-18]</td>
<td>6.2 (2.9)</td>
<td>5.7 (3.2)</td>
<td>.17</td>
</tr>
<tr>
<td>MMSE score, mean (SD) [range]</td>
<td>26.8 (2.6) [20-30]</td>
<td>26.6 (2.7)</td>
<td>27.1 (2.6)</td>
<td>.10</td>
</tr>
<tr>
<td>Current antidepressant prescription, No. (%)</td>
<td>157 (51.3)</td>
<td>100 (54.1)</td>
<td>57 (47.1)</td>
<td>.24</td>
</tr>
<tr>
<td>Current SCID diagnosis of MMDD, No. (%)</td>
<td>208 (68.0)</td>
<td>117 (63.2)</td>
<td>91 (75.2)</td>
<td>.03</td>
</tr>
<tr>
<td>HAM-D score, mean (SD) [range]</td>
<td>14.2 (7.8) [0-39]</td>
<td>13.7 (7.7)</td>
<td>15.0 (7.8)</td>
<td>.13</td>
</tr>
</tbody>
</table>

Abbreviations: ADL, activities of daily living; CDS, Chronic Disease Scale; Depression CAREPATH, Depression Care for Patients at Home; HAM-D, Hamilton Scale for Depression; IADL, independent activities of daily living; MMDD, major or minor depressive disorder; MMSE, Mini-Mental State Examination; SCID, Structured Clinical Interview for Axis I DSM-IV Disorders; SNF, skilled nursing facility.

<sup>a</sup> White vs other race categories.
<sup>b</sup> Includes Native American (n = 3) and Asian (n = 1).
<sup>c</sup>Data on 210 participants.
<sup>d</sup>Hospital to rehabilitation hospital or SNF to home health.
<sup>e</sup>Missing data for 5 or fewer participants unless otherwise noted.
Table 2. Principal ICD-9-CM Diagnoses of Individuals Using Medicare Home Health Services (2012 National Data and the Study Sample)

<table>
<thead>
<tr>
<th>Principal ICD-9-CM Major Diagnostic Categorya</th>
<th>ICD-9-CM Codes</th>
<th>National % (n = 3 460 000)b</th>
<th>Full Sample (N = 306)</th>
<th>Depression CAREPATH (n = 185)</th>
<th>Enhanced Usual Care (n = 121)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious and parasitic diseases, MDC 1</td>
<td>001-139</td>
<td>0.8</td>
<td>1 (0.3)</td>
<td>1 (0.8)</td>
<td></td>
</tr>
<tr>
<td>Neoplasms, MDC 2</td>
<td>140-239</td>
<td>3.2</td>
<td>13 (4.2)</td>
<td>8 (4.3)</td>
<td>5 (4.1)</td>
</tr>
<tr>
<td>Endocrine, nutritional, metabolic, immunity disorders, MDC 3</td>
<td>240-279</td>
<td>10.5</td>
<td>33 (10.8)</td>
<td>19 (10.3)</td>
<td>14 (11.6)</td>
</tr>
<tr>
<td>Diseases of the blood and blood-forming organs, MDC 4</td>
<td>280-289</td>
<td>1.7</td>
<td>2 (0.7)</td>
<td>1 (0.5)</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Mental disorders, MDC 5c</td>
<td>290-319</td>
<td>2.8</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Diseases of the nervous system and sense organs, MDC 6</td>
<td>320-389</td>
<td>4.7</td>
<td>13 (4.2)</td>
<td>7 (3.8)</td>
<td>6 (5.0)</td>
</tr>
<tr>
<td>Diseases of the circulatory system, MDC 7</td>
<td>390-459</td>
<td>27.6</td>
<td>109 (35.6)</td>
<td>66 (35.7)</td>
<td>43 (35.5)</td>
</tr>
<tr>
<td>Diseases of the respiratory system, MDC 8</td>
<td>460-519</td>
<td>9.3</td>
<td>27 (8.8)</td>
<td>20 (10.8)</td>
<td>7 (5.8)</td>
</tr>
<tr>
<td>Diseases of the digestive system, MDC 9</td>
<td>520-579</td>
<td>2.7</td>
<td>8 (2.6)</td>
<td>6 (3.2)</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>Diseases of the genitourinary system, MDC 10</td>
<td>580-629</td>
<td>3.2</td>
<td>11 (3.6)</td>
<td>8 (4.3)</td>
<td>3 (2.5)</td>
</tr>
<tr>
<td>Diseases of the skin and subcutaneous tissue, MDC 12</td>
<td>680-709</td>
<td>6.7</td>
<td>9 (2.9)</td>
<td>6 (3.2)</td>
<td>3 (2.5)</td>
</tr>
<tr>
<td>Diseases of the musculoskeletal or connective tissue, MDC 13</td>
<td>710-739</td>
<td>13.0</td>
<td>39 (12.7)</td>
<td>22 (11.9)</td>
<td>17 (14.0)</td>
</tr>
<tr>
<td>Congenital anomalies, MDC 14</td>
<td>740-759</td>
<td>0.1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Symptoms, signs, and ill-defined conditions, MDC 16</td>
<td>780-799</td>
<td>6.5</td>
<td>12 (3.9)</td>
<td>7 (3.8)</td>
<td>5 (4.1)</td>
</tr>
<tr>
<td>Injury and poisoning, MDC 17</td>
<td>800-999</td>
<td>6.3</td>
<td>29 (9.5)</td>
<td>15 (8.1)</td>
<td>14 (11.6)</td>
</tr>
<tr>
<td>Supplementary classification of factors V01-V82</td>
<td>V01-V82</td>
<td>36.3</td>
<td>58 (19.0)</td>
<td>37 (20.0)</td>
<td>21 (17.4)</td>
</tr>
</tbody>
</table>

Abbreviations: Depression CAREPATH, Depression Care for Patients at Home; ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; MDC, major diagnostic classification.

a Only the first listed or principal diagnosis has been used.
b The national data are from the Centers for Medicare and Medicaid Services14 (Table 76) among 3 460 000 persons served. Percentages based on the total of MDC 1 through MDC 17 V-codes may not sum to 100 because of rounding and the exclusion of MDC 11 and MDC 14 from the national database owing to small numbers. Consistent with the presentation of national data, the total of MDC 1 through MDC 17 is 100.0%, and V-code percentages are determined separately.

c By design, the study did not recruit patients from behavioral health programs; therefore, no patient has mental disorder as a primary diagnosis.

Primary Analyses

Improvement in depressive symptoms (HAM-D scores) from baseline was analyzed with the full sample (N = 306) in a mixed-effects model for months 3, 6, and 12 with intervention, time squared, and intervention × time interaction as fixed effects and adjusted for agency and nurse team cluster, IADLs, the use of antidepressants, the presence of MMDD, sex, and living alone. Adjusted HAM-D scores (Depression CAREPATH vs enhanced usual care) did not differ at 3 months (10.5 vs 11.4, P = .26) or at 6 months (9.3 vs 10.5, P = .12). The 12-month HAM-D score difference reached statistical significance (8.7 vs 10.6, P = .05), but intervention × time interaction was not significant (P = .13).

Secondary Analyses

The moderat analysis examined depression severity (HAM-D scores) over time in 4 groups that were defined by both intervention status and BDS. The analysis found no significant (P = .12) 3-way interaction (BDS × intervention × time) after controlling for IADLs, living alone, and agency and nurse team cluster as covariates. In stratified analysis of participants with a HAM-D score of 10 or higher, time (P < .001), time squared (P < .001), and intervention × time interaction (P = .02) all differed significantly from zero after controlling for baseline antidepressant use, IADLs, living alone, and agency and nurse team cluster as fixed covariates. These findings indicate that HAM-D scores decreased over time in both groups, but the reduction was significantly greater in the Depression CAREPATH group than in enhanced usual care group (Figure 2). The group difference in HAM-D scores was tested at each follow-up point (Table 3).40 The Depression CAREPATH participants had significantly lower HAM-D scores than the enhanced usual care participants at 3 months (14.1 vs 16.1, P = .04), at 6 months (12.0 vs 14.7, P = .02), and at 12 months (11.8 vs 15.7, P = .005). Change in HAM-D scores from baseline to 1 year also differed significantly between groups (5.6 points for the intervention group vs 3.1 points for the enhanced usual care group, P = .02). Among less depressed participants (HAM-D score <10), no difference was observed between groups (P = .90 for intervention × time interaction).
was reanalyzed using a 6-item HAM-D mood subscale. Among patients with HAM-D scores of 10 or higher, intervention × time interaction effect was not significant ($P = .15$). Stratified analysis resulted in similar conclusions as BDS; hence, the results are not presented herein.

Mixed-effects model analyses with patients having HAM-D scores of 10 or higher found no significant difference in the intervention effect by baseline antidepressant use ($P = .84$ for intervention × time × antidepressant use interaction and $P = .57$ for intervention × antidepressant use interaction). Intervention vs enhanced usual care differences in 12-month HAM-D score change from baseline did not differ ($P = .84$) by baseline antidepressant use (6.0 vs 3.5 among antidepressant users and 4.8 vs 2.7 among nonusers).

To explore the influence of somatic symptoms, the model was reanalyzed using a 6-item HAM-D mood subscale. Among patients with HAM-D scores of 10 or higher, intervention × time interaction effect was $P = .10$ after controlling for baseline antidepressant use, IADLs, living alone, and agency and nurse team cluster. The Depression CAREPATH participants had significantly lower mood scores than the enhanced usual care participants at 6 months (4.6 vs 5.5) and at 12 months (4.7 vs 6.0) ($P = .03$ for both).

The effect on service delivery was explored using administrative data. Among those with HAM-D scores of 10 or higher, the mean duration of service did not differ between groups (64.1 days for the Depression CAREPATH vs 64.7 days for enhanced usual care, $P = .94$). Visit data (available from only one agency) showed no group differences in the mean number (11.0 vs 12.4 visits, $P = .42$) or duration (54.5 vs 59.9 minutes, $P = .18$) of nursing visits.

**Discussion**

The principal finding in this study is that, among medical home health care patients who screen positive for depression, a home health nursing intervention did not improve depression scores overall. However, among the subgroup with more significant depression, the intervention was associated with greater decrease in depressive symptoms than enhanced usual care. The difference between groups was significant at 3 months, growing larger and more clinically substantial during 1 year.

The potential implications of these results need to be placed in the context of study limitations. First, agencies were diverse in size and location but were not strictly representative of certified home health care agencies. Although agencies had minimal research experience, their leadership’s agreement to participate suggests greater support for practice change than average. Second, study participants represent only patients with sufficient cognitive functioning and willingness to participate in research. Third, we cannot explain higher consent rates among minority and younger patients. These factors and attrition due to death, illness, or cognitive decline may affect generalizability of our results. With these caveats, our findings can be examined from several perspectives.

Study participants were homebound older adults with substantial medical burden and disability. Like most (>97%) Medicare Home Health patients, their primary diagnosis was medical or surgical and not mental. The heterogeneity in patients’ primary diagnoses is consistent with the national profile of home health care patients. Depression adds to personal debility, family burden, and risk of hospitalization, falls, and other poor outcomes. Among patients with clinically significant depression, the Depression CAREPATH intervention was
associated with a 5.6-point decline in HAM-D score, indicating substantial changes in depression severity (eg, from moderate to mild or from mild to minimal) and consistent with interventions in primary care.\(^5^6\) Effect sizes at 6 and 12 months (Cohen's d, 0.32 and 0.49, respectively) were also consistent with primary care studies\(^4^5\-\^4^8\) and considered beneficial by the Community Preventive Services Task Force.\(^4^9\) However, as in primary care studies, most intervention patients herein continued to experience substantial depressive symptoms, despite improvement. Both biological and psychosocial factors affect depression course and treatment response in older adults, and this finding points to both the limitations of the home health care intervention and the importance of ongoing individualized treatment decision making.\(^5^0\-\^5^2\)

Medicare strengthened depression screening by adding the PHQ-2 to the OASIS. Like most screens, the PHQ-2 is not a definitive measure but identifies patients with a higher likelihood of having clinically substantial symptoms. The study's negative finding of no intervention effect among all screen-positive patients is consistent with this goal of screening. The Depression CAREPATH uses the PHQ-9, a brief measure of depression severity,\(^2^7\) to help nurses narrow screened-positive patients to those with greatest need. The findings suggest that investing in further evaluation is efficient and effective.

Our finding of no intervention effect among patients with mild depression (HAM-D score, <10) is consistent with the protocol's instructions to only monitor milder symptoms, which may in effect resemble usual care. This result is similar to interventions tested in primary care for subsyndromal depression.\(^2^1\)-\(^5^3\) However, it differs in that mild symptoms generally improved in primary care, whereas symptoms persisted in home health care. These results suggest that more active interventions may be needed or that subsyndromal symptoms may indicate more stable phenomena.\(^5^4\)-\(^5^5\)

Medicare recognizes psychiatric home health care as a billable service if patients' primary diagnosis is a mental disorder (International Classification of Diseases, Ninth Revision, Clinical Modification codes 290-319) requiring active treatment and if services are provided by a “psychiatrically trained nurse.”\(^5^6\) The impetus for developing the Depression CAREPATH was evidence that depression is prevalent and burdensome among medical home health care patients, coupled with reluctance expressed by administrators to develop specialty services, increase personnel, or reduce nurse productivity. Researchers worked with clinicians and administrators to develop an intervention that was clinically effective, feasible, and acceptable to medical nurses. The resulting Depression CAREPATH followed principles of collaborative depression care, an approach that fits naturally with home health care, where nurses serve as the eyes and ears of physicians who are responsible for these services.\(^5^7\) However, the Depression CAREPATH modified collaborative care to fit routine home health care practice. Clinical tasks were defined in home health care terms and were consistent with job expectations.\(^5^5\)-\(^5^8\)

Nurses were not asked to make treatment decisions (eg, prescribe) or provide psychotherapy. Rather, they were asked to care for depression as they care for other chronic diseases.

Exploratory analyses found no difference in the effect of the intervention by whether or not patients were already taking antidepressants. This finding is important because half of the participants were taking antidepressants, many with guideline-consistent dosages. In this context, active symptoms suggest that the current antidepressant regimen is ineffective and that patients may benefit from a change (eg, dosage, switching, augmentation, or the nonspecific benefit of care management).\(^5^9\)

Evidence that medical home care nurses can effectively integrate depression care into routine practice is also important given the report by the Institute of Medicine\(^1^6\) documenting the scarcity of qualified mental health providers in home health care and elsewhere for the rapidly aging population. The report recommends expanding capacity by building on skills of other clinicians and paraprofessionals. Therefore, while this study focused on home health care, the approach may be relevant to other populations.

Of importance to home health care administrators, the Depression CAREPATH was designed to fit within routine practice. Depression management was integrated into already scheduled visits and did not require or result in additional or longer home visits. The protocol was simple enough to integrate key elements into 5 commercial clinical software systems.

From the broader perspective, the effect of the intervention continued to grow during 1 year. Medicare pays for short-term home health care (eg, 60-day episodes).\(^1^4\) This long-term benefit may indicate a cumulative effect, starting perhaps with assessing depression in the home environment and integrating depression into both care coordination and hand-off. These tasks are consistent with many innovative models of transitional and posthospitalization care, suggesting that addressing depression is both feasible and potentially useful.\(^6^0\)-\(^6^5\)

Conclusions

Clinically significant depression is common among patients receiving Medicare Home Health services and is associated with poor outcomes. Medicare recommends depression screening and intervention, but the clinical needs of home health care patients, the scarcity of mental health specialists, and the structure and practice of home health care pose challenges to this goal. This effectiveness trial demonstrates that home health care nurses can effectively integrate DCM into routine practice, with the clinical benefit to moderate to severely depressed patients extending beyond the home health care service period.
Health Policy and Research, Well Cornell Medical College, New York, New York (Banerjee); Montefiore Home Health Agency, Bronx, New York (Pickett, Joachim); Rhode Island Hospital, Providence (Sheeran); Department of Psychiatry and Human Behavior, The Warren Alpert Medical School of Brown University, Providence, Rhode Island (Sheeran); Brookdale Center for Healthy Aging, Hunter College, New York, New York (Ghesquiere); Triumph Home Health Care, Livonia, Michigan (Zukowski): United HomeCare, Miami, Florida (Rosas); Visiting Nurse and Hospice for Vermont and New Hampshire, West Lebanon, New Hampshire (McLaughlin); Baptist Home Health Network, Little Rock, Arkansas (Pledger); Penn Care at Home, Wyndham, Pennsylvania (Doyle).

Author Contributions: Dr Bruce had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Bruce, Raue, Reilly, Greenberg, Meyers, Sheeran, Leon.

Acquisition, analysis, or interpretation of data: Bruce, Raue, Greenberg, Meyers, Pickett, Ghesquiere, Zukowski, Rosas, McLaughlin, Pledger, Doyle, Joachim, Banerjee.

Drafting of the manuscript: Bruce, Raue, Reilly, Greenberg, Meyers, Banerjee.

Critical revision of the manuscript for important intellectual content: Bruce, Raue, Reilly, Greenberg, Meyers, Banerjee, Pickett, Sheeran, Ghesquiere, Zukowski, Rosas, McLaughlin, Pledger, Doyle, Joachim.

Statistical analysis: Bruce, Greenberg, Banerjee.

Obtained funding: Bruce, Raue, Leon.

Administrative, technical, or material support: Bruce, Meyers, Sheeran, Ghesquiere, Zukowski, Rosas, McLaughlin, Pledger, Doyle, Joachim.

Study supervision: Bruce, Raue, Reilly, Greenberg, Pickett, Sheeran, Zukowski, McLaughlin, Pledger, Doyle, Joachim.

Conflict of Interest Disclosures: Dr Bruce reported receiving personal fees for consultation from McKesson and other support from Medispan. Dr Pickett reported receiving salary from Montefiore Medical Center’s Department of Psychiatry. Ms Zukowski reported receiving personal fees from Zone Program Integrity Contracts. No other disclosures were reported.

Funding/Support: This study was supported by grants R01 MH082425 (Dr Bruce), P30 MH083943, T32 MH079132, T32 MH079153 (Dr Bruce), and K01 MH073783 (Dr Sheeran) from the National Institute of Mental Health.

Role of the Funder/Sponsor: The funding source had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: The content of this article is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Additional Contributions: The late Andrew C. Leon, PhD (Well Cornell Medical College), collaborated in the study design and preparation of the grant proposal. Judy C. Pomerantz, RN, MS, PMHHCNS-BS (Dominican Sisters Family Health Services), provided consultation and training in depression care management. Yuhua Bao, PhD (Well Cornell Medical College), provided consultation. The following research assistants helped with the day-to-day data collection: Kisha N. Bazelaix, PhD, Stephanie H. Charles, BA, Rebecca M. James, MA, Jennifer H. Lotterman, MS, Christina M. Mele, BS, Melissa A. Mezo, BS, and Daniel R. Sugrue, BA (all from Well Cornell Medical College). All the people acknowledged above were compensated for their work on this study. Finally, we thank all the investigators, clinicians, patients, and their families for their contributions.

REFERENCES


