

BE-ACTIV for Depression in Nursing Homes: Primary Outcomes of a Randomized Clinical Trial

Suzanne Meeks,¹ Kimberly Van Haitsma,² Ben Schoenbachler,³ and Stephen W. Looney⁴

¹Department of Psychological and Brain Sciences, University of Louisville, Kentucky.

²Polisher Research Institute, Abramson Center for Jewish Life, North Wales, Pennsylvania.

³Department of Psychiatry and Behavioral Science, University of Louisville, Kentucky.

⁴Department of Biostatistics and Epidemiology, Georgia Regents University, Augusta.

Objectives. To report the primary outcomes of a cluster randomized clinical trial of Behavioral Activities Intervention (BE-ACTIV), a behavioral intervention for depression in nursing homes.

Method. Twenty-three nursing homes randomized to BE-ACTIV or treatment as usual (TAU); 82 depressed long-term care residents recruited from these nursing homes. BE-ACTIV participants received 10 weeks of individual therapy after a 2-week baseline. TAU participants received weekly research visits. Follow-up assessments occurred at 3- and 6-month posttreatment.

Results. BE-ACTIV group participants showed better diagnostic recovery at posttreatment in intent-to-treat analyses adjusted for clustering. They were more likely to be remitted than TAU participants at posttreatment and at 3-month posttreatment but not at 6 months. Self-reported depressive symptoms and functioning improved in both groups, but there were no significant treatment by time interactions in these variables.

Discussion. BE-ACTIV was superior to TAU in moving residents to full remission from depression. The treatment was well received by nursing home staff and accepted by residents. A large proportion of participants remained symptomatic at posttreatment, despite taking one or more antidepressants. The results illustrate the potential power of an attentional intervention to improve self-reported mood and functioning, but also the difficulties related to both studying and implementing effective treatments in nursing homes.

Key Words: Depression—Nursing homes—Intervention—Clinical trial.

IN this paper, we report the primary outcomes of a clinical trial of a behavioral intervention for depression tailored for nursing home residents. Depression is prevalent in nursing homes and raises risk for medical morbidity, mortality, and poor quality of life. Although there are evidence-based treatments (EBTs) for depression in older adults, nursing home settings present a number of delivery and implementation challenges, as well as special characteristics of the population, that limit the utility of these EBTs for residents. We used a combined effectiveness/efficacy approach for developing and testing an intervention that could address some of these challenges. The Behavioral Activities Intervention (BE-ACTIV) involves 10 weekly sessions delivered by a mental health therapist (MHT). The MHT works collaboratively with activities staff members.

Rates of major and minor depression, and subsyndromal depressive symptoms, are higher in nursing homes than among community dwellers (Fullerton, McGuire, Feng, Mor, & Grabowski, 2009; Teresi, Abrams, Homes, Ramirez, & Eimicke, 2001). Depression among those in residential care is related to decreased cognitive status, functional capacity, clinician-rated health, pain (Katz & Parmelee, 1997), greater use of nursing time (Fries et al., 1993), suicidality (Reynolds et al., 1998), and increased

mortality (Rovner et al., 1991). The common comorbidity of depression and dementia further increases risks (Kales et al., 2005), including increased agitation and aggression (Lyketos et al., 1999), increasing the amount of care, and the stress on the caregiver. Treatments for depression in nursing homes must be applicable to the range of depressive syndromes seen in these settings and to those residents with cognitive impairment.

Antidepressant medications are sometimes effective in treating frail elders (Snowden, Sato, & Roy-Byrne, 2003) but may fail to improve functional disability or self-care (Katz, Simpson, Curlik, & Parmelee, 1990) or mitigate bereavement (Reynolds et al., 1999) or hopelessness (Szanto, Reynolds, Conwell, Begley, & Houck 1998). Antidepressants produce an increased risk of side effects (Thapa, Gideon, Cost, Milam, & Ray, 1998). They are increasingly used in nursing homes, but there are concerns about the typical quality of medication management (Gaboda, Lucas, Siegel, Kalay, & Crystal, 2011; Shah, Schoenbachler, Streim, & Meeks, 2012; Weintraub, Datto, Streim, & Katz, 2002). These shortcomings suggest the need for psychosocial interventions, but psychotherapy is rarely used in nursing homes (Shah et al., 2012; Snowden, Piacitelli, & Koepsell, 1998).

Hyer, Carpenter, Bishmann, and Wu (2005) reviewed 19 clinical trials for psychosocial interventions in nursing homes that included depressive symptoms as outcomes. Despite noting numerous methodological limitations, including failure to select participants based on well-defined depression criteria, lack of treatment manuals, small sample sizes, and lack of follow-up assessments, they concluded that there is preliminary support for the efficacy of psychosocial interventions to alleviate depressive symptoms. Since that review, eight randomized, controlled studies have been published (Brodaty et al., 2003; Cernin and Lichtenberg, 2009; Hyer, Yeager, Hilton, & Sacks, 2009; Jones, 2003; Hsu & Wang, 2009; Sood, Cisek, Zimmerman, Zaleski, & Fillmore, 2003; Tappen & Williams, 2009; Tsai, Wong, Tsai, & Ku, 2008). Although promising, most of these trials were very small; the two larger trials (Brodaty et al., 2003; Tsai et al., 2008) were carried out in Australia and Taiwan, respectively, and showed no group \times time differences at posttreatment. There remains the need for carefully designed controlled studies of interventions for depression among nursing home residents.

BE-ACTIV was developed collaboratively with nursing home staff to be feasible within current staffing structures and mental health reimbursement systems. The development process and theoretical rationale for the intervention have been presented elsewhere (Meeks & Depp, 2002; Meeks, Looney, Van Haitsma & Teri, 2008; Meeks, Teri, Van Haitsma, & Looney, 2006; Meeks, Young, & Looney, 2007). The conceptual model is based on a revised version of Lewinsohn's (1974) original behavioral model of depression (Lewinsohn, Hoberman, Teri, & Hautzinger, 1985), which posits that stressful circumstances disrupt behavioral regularity, disrupting the balance between positive and negative affect. Heightened negative self-awareness diminishes the ability to regulate positive affect, perpetuating dysphoria and inhibiting the person's ability to maintain emotional equilibrium. Nursing homes and other institutional settings further limit access to positive activities (Hopko, Lejuez, LePage, Hopko, & McNeil, 2003). BE-ACTIV is designed to restore the balance of positive to negative affect by affording consistent opportunity to experience positive reinforcement from the environment. We adapted a treatment manual developed for family caregivers of dementia patients (Teri, Logsdon, Uomoto, & McCurry, 1997) to create a hybrid, collaborative, individualized therapy that utilizes a mental health professional but also involves nursing home activity staff (Meeks et al., 2008). The current paper reports on the results of a cluster randomized clinical trial of BE-ACTIV in 23 nursing homes. We report the outcomes for the following primary hypotheses.

H1: As compared with nursing home residents receiving treatment as usual (TAU), residents randomized to BE-ACTIV will, after 10 weeks, be more likely to show diagnostic recovery. In addition, treated residents

will show symptomatic improvement in depression and functioning (social and daily activities).

H2: As compared with nursing home residents receiving TAU, residents randomized to BE-ACTIV will continue to show superior outcomes related to diagnosis, symptoms, and functioning at 3- and 6-month posttreatment.

METHOD

A two-group, cluster randomized, control group design compared BE-ACTIV and a TAU control group. The unit of randomization was the nursing home, with residents nested within nursing homes; nursing homes were blocked by size (greater or fewer than 100 beds). The treatment phase was 10 weeks following a 2-week baseline assessment period. Participants were reassessed on diagnosis and symptom measures immediately posttreatment. There were two follow-up assessments, at 3- and 6-month posttreatment.

Treatment Groups

Treatment as usual.—Residents in TAU nursing homes continued to receive the treatments already available to them, which for most meant receiving antidepressants. Research staff visited them weekly for 12 weeks to collect self-rated mood data, spending 5–30 min per visit. Research staff supervised by the third author reviewed treatment records to code medication management and other treatments. To control for the effects of staff participation in training, the first author provided a 2-hr training session for activities staff in TAU facilities that was equal in length to the training provided in the treatment homes, but of different content, focused on understanding dementia and roles of activity staff in managing behavior problems, but not on depression or pleasant events.

Behavioral Activities Intervention.—BE-ACTIV involved two baseline assessment visits (same as TAU group) and 10 weekly sessions between the resident and a MHT, during which the MHT assessed the availability and individual reinforcement value of pleasant activities (Meeks et al., 2008). Staff facilitators, who assisted the resident to carry out the planned activities, were invited to Sessions 1, 5, and 10. MHTs also met weekly with staff facilitators at each treatment facility without the resident present. MHTs were clinical psychology doctoral students who completed a training seminar and practicum on the intervention. MHTs exceeded a criterion of 80% adherence with manual expectations across 10 sessions of treatment with at least one clinical case before taking on a study client. Staff facilitators participated in a 2-hr training program on depression, pleasant events, and behavior management by the first author and received a manual outlining staff responsibilities. To insure treatment integrity, we provided staff members with resources such as craft supplies or audio players when needed to carry out some of the requested pleasant

events. [Supplementary Table 1](#) summarizes the BE-ACTIV treatment sessions.

Inclusion and Exclusion Criteria

Nursing home staff identified residents who were: (a) aged 55 or older, residing in long-term care beds with an expected stay of 3 months or more, (b) diagnosis, positive facility screen, or treatment of depression, and (c) staff belief they were sufficiently cognitively intact to give consent. Exclusion criteria included: (a) under the care of or referral to Hospice for a terminal condition, (b) medical condition deemed unstable or terminal by nursing staff, (c) physical condition so deteriorated the resident was unable to participate in either self- or other-initiated activities, and (d) for the BE-ACTIV group only, resident receiving weekly psychotherapy. Research staff further screened consenting residents using the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorder (DSM)-IV (SCID-IV), the Geriatric Depression Scale (GDS), and the Mini-Mental State Examination (MMSE). Residents scoring below 14 on the MMSE were excluded (see [McGivney, Mulvihill, & Taylor, 1994](#)). Residents were included if they had a GDS score of 11 or above and met criteria for DSM-IV depressive disorder.

Measures

Mini-Mental State Examination.—The MMSE ([Folstein, Folstein, & McHugh, 1975](#)) is one of the most widely used mental status examinations for dementia screening ([Tombaugh & McIntyre, 1992](#)). The MMSE consists of 11 items that cover orientation, registration, attention/calculation, recall, and language function. Scores range from 0 to 30.

Geriatric Depression Scale.—The GDS ([Brink et al., 1982](#)) is a 30-item, self-report depression screening scale developed for use with older adults. The psychometric properties of the scale are well established for a variety of settings (e.g., [Koenig, Meador, Cohen, & Blazer, 1988](#); [Snowdon, 1990](#)). [McGivney and colleagues \(1994\)](#) found 84% sensitivity and 91% specificity rates in cognitively impaired patients with scores above 14, using a cutting score of 11. Internal consistency for this sample was .70. The GDS was given at baseline, posttreatment, and at 3- and 6-month follow-ups.

Demographic data.—Participants' age, sex, race, former occupation, and source of payment were collected from the residents' medical charts at the nursing homes at baseline.

Health data.—Medical data were extracted from nursing home charts at baseline, posttreatment, and 3- and 6-month posttreatment. Licensed nursing homes use the standardized Minimum Data Set (MDS) on all residents, completed annually and updated quarterly by facility staff. We used data from the most recent complete MDS and quarterly update. The

version of the MDS used by the facilities changed from 2.0 to 3.0 during the study; medical and functional scales presented here are from the MDS 2.0, and the data from charts that included 3.0 were cross-walked to 2.0 items where possible. The scales reported here include number of current (nonmental health) disease diagnoses, number of medications prescribed, and activities of daily living (ADL) impairment. This latter scale consists of 10 ADL items rated from 0 to 4 (*independent to total assist*) or 8 (*not performed at all during rating period*) and summed for a total scale score. We also report weight in pounds and number of days on antidepressants, anxiolytics, hypnotics, and antipsychotics from the MDS data.

Psychotropic medication use.—At the time that the MDS was extracted from the charts, research assistants recorded all psychotropic drug use as indicated in the medical record.

Structured Clinical Interview for DSM-IV.—We used the mood disorders section of the SCID-IV, Non-Patient Research Version ([First et al., 2002](#)), to establish research diagnoses. When necessary, interviewers corroborated information from family members, staff, or from nursing home medical charts. The first author completed the pretreatment interviews, and the posttreatment and follow-up interviews were completed by the third author, who remained blind to condition throughout the study. Both interviewers had completed recommended training procedures for the SCID ([Ventura, Liberman, Green, Shaner, & Mintz, 1998](#)). The two interviewers achieved diagnostic reliability of .75 or better (kappas or intraclass correlations) on practice videotapes before conducting study interviews. Final diagnoses were arrived at by consensus between the two interviewers.

The primary outcome for the BE-ACTIV versus TAU comparison was diagnostic recovery. All cases were coded by two raters (the first and second authors). Kappa between the two raters was .84 for posttreatment outcomes, $p < .001$ ($N = 82$). Diagnostic recovery codes at posttreatment were: unchanged from baseline diagnosis (0), improved (1), remitted (2), or worsened (3). Those who had the same SCID diagnosis at Week 12 were coded as unchanged. Those who went from major depression (major depressive episode [MDE]) to MDE in partial remission, or from MDE to a lesser form of depression (e.g., depression not otherwise specified), and who still had two or more depressive symptoms coded on the SCID, were coded as "improved." Those who either could not be given a diagnosis because of lack of symptoms at posttreatment, were coded MDE in full remission, or were coded MDE in partial remission with no more than one symptom in the week prior to the interview, were coded as "remitted." In intent-to-treat analyses, those who did not complete a posttreatment interview were coded as unchanged from their baseline diagnosis. At the 3- and 6-month follow-ups, the same codes were used, except the last code was "relapsed or worsened." This category included those who had improved at the previous

assessment and then worsened, as well as those who had worsened at the previous assessment and were still unimproved. The “improved” category at the two follow-up points included those who had newly improved and those who had maintained their improvement from the prior assessment but were still not fully remitted. In intent-to-treat analyses, when there were data missing, the participant was coded as unchanged from the prior assessment.

Dartmouth COOP Scales of Functioning.—The COOP chart is a stimulus comprised a title, a question, and a chart of five response choices (Nelson et al., 1987). Each response choice is represented both as a verbal rating (e.g., “No difficulty at all”) and as an illustrative drawing. The COOP charts have been used widely to assess functioning in frail elders with alphas ranging from .42 to .90 and test–retest average of .93 (Haywood, Garratt, & Fitzpatrick, 2005). COOP chart scores compare favorably with results from longer functional status measures (Haywood et al., 2005; Unal et al., 2001). They were administered during baseline, posttreatment, and follow-up interviews. Hypothesized outcomes were for two of the COOP charts, daily activities and social functioning.

Treatment integrity.—We assessed treatment integrity at the client, therapist, and staff levels. The first author coded digital recordings and reviewed sessions in weekly supervision with the MHTs. MHTs also completed self-ratings after every session. Scales used for these ratings were adapted from those used by Teri and colleagues (1997) and our pilot work. The scales differed slightly for each session based on content of the sessions; items were rated 0 or 1 to reflect whether the therapist accomplished tasks from the manual. For each session, there were also three quality ratings, rated from 0 (*not at all*) to 2 (*completely*), regarding the degree to which the therapist responded to the client’s needs and avoided irrelevant techniques, and the overall quality of the session. Thus, two scores were created for each session: an adherence score that counted the number of 1s for the adherence items and a quality score summing the ratings for the three quality items. The MHTs also completed weekly ratings on staff follow-through with activities, and recorded the clients’ effort and success in completing the activity homework, using formats developed in our pilot work.

Treatment satisfaction.—At posttreatment, staff and residents involved in BE-ACTIV completed questionnaires to assess their satisfaction with the treatment and its outcomes. These questionnaires were adapted from the satisfaction scales used in the Fort Bragg Evaluation Project (Bickman, Heflinger, Pion & Behar, 1992), which have shown excellent reliability (alphas ranging from .70 to .98) when used with both white and black respondents (Brannan, Sonnichsen, & Heflinger, 1996).

Nursing home characteristics.—The following nursing home characteristics were downloaded from the CMS Nursing

Home Compare database: size, payer type, owner, survey deficiencies, staffing ratios, and federal quality indices.

Recruitment and Attrition

Data collection occurred between September 2008 and July 2012. Twenty-four facilities agreed to participate (one facility produced no eligible participants; see [Supplementary Table 2](#)). The majority of the facilities were in the Louisville, KY metropolitan area, 19 in Kentucky and 5 in Indiana; 5 were in rural communities. All were corporately owned; 18 were for-profit, 5 nonprofit, and 1 had nonprofit church-affiliated ownership. Thirteen facilities were assigned to BE-ACTIV, and 11 to TAU. Five facilities qualified as “small” according to our 100-bed criterion. Independent samples *t* tests showed no significant differences between BE-ACTIV and TAU facilities in size or quality measures, except that the BE-ACTIV facilities had significantly higher staffing levels for certified nursing assistants.

Once a facility agreed to participate, they provided research staff with a list of potentially eligible residents. Research staff members handled consent procedures. [Figure 1](#) shows recruitment outcomes and attrition. Intent-to-treat analyses were performed on 82 participants, 42 in BE-ACTIV and 40 in TAU.

Linear mixed effects regression models (MRMs) were used to compare completers and dropouts on continuous and ordinal categorical demographic variables and medical characteristics. Generalized linear mixed effects models (GLMMs) were used to compare dichotomous variables. For nominal categorical variables, the estimated intracluster correlation was used to adjust the standard chi-square comparison. All analyses were performed to adjust for nesting of participants within nursing homes. All tests were performed at the .05 significance level. Statistical analyses used SAS 9.3 for Windows (SAS Institute Inc., Cary, NC).

The primary reason for attrition was change in health status, including 14 deaths and 14 hospitalizations or other illness events. Four individuals in the BE-ACTIV group voluntarily withdrew during the treatment phase, compared with one TAU participant. This difference did not reach statistical significance, $\chi^2 = 3.18$, $DF = 1$, $p = .074$, adjusted χ^2 p value = .168, and the apparent imbalance between groups disappeared at the 3-month follow-up. There were no significant differences between people who completed the study and those who dropped out on demographics, MDS health data, psychotropic medications, physician and hospital visits, GDS, or any of the COOP items.

Sample Characteristics

Participants had an average age of 75.16 (standard deviation [*SD*] = 12.11), had completed a mean of 11.56 years of education ($SD = 3.35$), and had been in the facility an average of 37.70 months ($SD = 74.56$). A total of 34.6% were men, 92.6% were white of European origin. They had an average

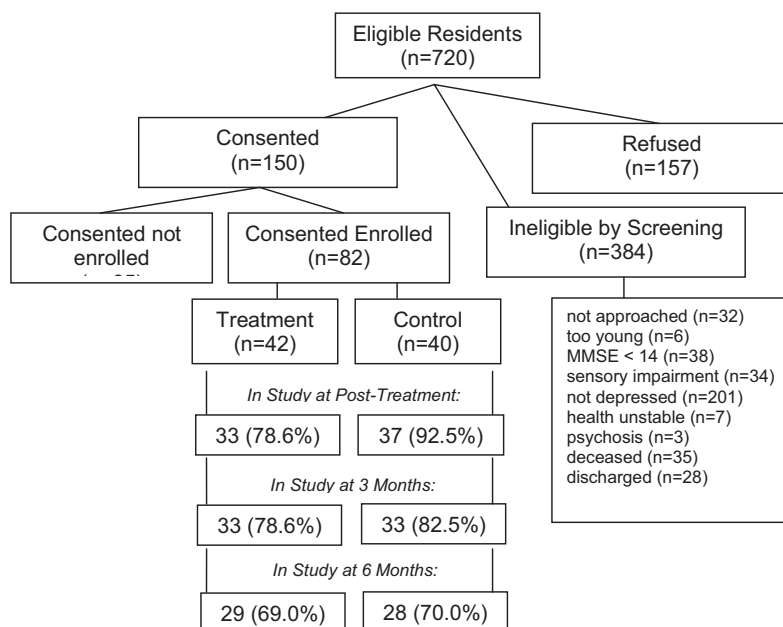


Figure 1. CONSORT diagram.

of 9.31 ($SD = 4.20$) nonmental health medical diagnoses and more than 81% were receiving antidepressant medications. To examine sample representativeness, we randomly reviewed 20% of charts of nonstudy residents (or a minimum of 20) from participating facilities. These comparisons can be seen in [Supplementary Table 3](#). Examination of nonstudy participants is complicated by the fact that many of those not in the study were not depressed. Thus, differences between those in the study and those not in the study have to be interpreted in the context of known risk factors for depression in this population. We compared study participants with the randomly selected nonstudy residents using MRMs and GLMMs, as in the comparison of completers and dropouts. Participants were different from nonstudy residents on a number of variables known to be established depression risk factors ([Whitbourne & Meeks, 2010](#)): they were younger ($t = 2.90$, $DF = 477$, $p = .004$), more likely to be white ($t = 2.46$, $DF = 481$, $p = .014$), had more medical diagnoses ($t = 4.50$, $DF = 517$, $p < .001$), lower ADL functioning ($t = 2.56$, $DF = 518$, $p = .011$), higher average weight ($t = 3.12$, $DF = 513$, $p = .002$), and were taking more medications ($t = 4.03$, $DF = 344$, $p < .001$) than the randomly selected patient charts. Not surprisingly, they were also more likely to be taking antidepressants ($t = 3.94$, $DF = 494$, $p < .001$) and anxiolytics ($t = 3.38$, $DF = 494$, $p < .001$). The groups were comparable on gender, length of time in the facility, pay type, former occupation, years of education, frequency of hospital visits, emergency room visits, physician visits, and mental health treatments.

Baseline comparisons of the BE-ACTIV and TAU groups on demographics and MDS health variables showed that the groups were similar on the majority of characteristics compared. However, the BE-ACTIV group had fewer days on an antidepressant at baseline ($t = 2.18$, $DF = 54$, $p = .034$,

more education ($t = 2.46$, $DF = 60$, $p = .017$), and a larger number of physician visits ($t = 2.56$, $DF = 6.6$, $p = .022$) than the TAU group (see [Supplementary Table 3](#)). Based on MRM and GLMM analyses, none of these covariates were significantly associated with the primary outcomes, so no adjustment was made for them as confounders in the analyses examining the effectiveness of the intervention. Only nine (21.4%) of the BE-ACTIV group and six (15.0%) of the TAU group were not taking at least one antidepressant at baseline. In addition to those on one antidepressant (45.2% and 50.0%, respectively, in the two groups), approximately a quarter of each group (27.5% and 23.8%, respectively) were on two antidepressants, and 9.5% and 5%, respectively, were on three. One member of the TAU group was on four antidepressants. The mean duration of antidepressant usage for the primary antidepressant was approximately 9 months, although widely variable in both groups. Consistent with our broad inclusion criteria, participants presented with a range of depressive disorders. The modal current diagnosis was MDE: 69.1% met symptomatic criteria for MDE at baseline. The rest of the sample met criteria for other depressive disorders. A chi-square analysis comparing BE-ACTIV and TAU groups on baseline diagnosis was significant (Fisher's exact $\chi^2 = 13.97$, $DF = 8$, $p = .041$, adjusted $\chi^2 p$ value = .041); there were proportionally fewer participants diagnosed with major depressive disorder and more diagnosed with minor depression in the BE-ACTIV group than in the TAU group.

RESULTS

Diagnostic Recovery

Diagnostic recovery differences between BE-ACTIV and TAU groups were examined using MRMs and GLMMs.

Cramer's V statistic, which is equivalent to Cohen's measure of effect size w for cross-classified data when there are two rows and two columns (Cohen, 1988), was used to describe the effect size for the significant comparisons. According to Cohen's criteria, $w = .1$ denotes a small effect size, $w = .3$ denotes medium, and $w = .5$ denotes a large effect size for a 2×2 table. The advantage of using V as a measure of effect size is that it is valid with any number of rows and any number of columns.

We used intent-to-treat analyses for all diagnostic outcomes ($N = 82$). The results are shown in Table 1. The BE-ACTIV versus TAU group comparison yielded a chi-square value of 10.38, $DF = 3$, $p = .008$, adjusted χ^2 p value = .035, Cramer's $V = .36$. Table 1 shows that 57.5% of TAU participants, and 45.3% of BE-ACTIV, were unchanged or worsened. The treated group was more likely than the controls (45.2% vs 15.0%) to be fully remitted posttreatment, whereas the control group was more likely (27.5% vs 9.5%) to be improved but not remitted. All drop-outs posttreatment were in the unchanged category for both groups, and results for completers are similar to intent-to-treat analyses. We collapsed outcome categories into improved/not improved, and in these comparisons, the proportion of those improved in each group (54.8% vs 42.5% for BE-ACTIV vs TAU, respectively) was not significantly different. When we collapsed outcome categories into remitted/not remitted, however, the difference in proportion remitted was significant, in favor of BE-ACTIV, 45.2% versus 15.0% remitted ($\chi^2 = 8.84$, $DF = 1$, $p = .003$, adjusted χ^2 p value = .002; Cramer's $V = .33$). Because of the group difference on proportion of participants with major depressive disorder, we compared treatment groups on both recovery and improvement outcomes across diagnostic categories. The treatment group had the greatest advantage over TAU for those with major depression.

Diagnostic outcomes for the 3-month and 6-month follow-ups are summarized in Figure 2. At 3-month posttreatment, intent-to-treat results were nonsignificant, $\chi^2 = 7.93$, $DF = 3$, $p = .061$, adjusted χ^2 p value = .061. However, for those who remained in the study at 3 months, participants in BE-ACTIV were significantly more likely than TAU controls to have improved or remitted, $\chi^2 = 8.80$, $DF = 3$, $p = .032$, adjusted χ^2 p value = .032. The effect size of this group difference, based on Cramer's V , was .38. In the BE-ACTIV group, 66.7% of those remaining in the study had either improved or remitted by 3 months, as compared

with only 40.7% of the TAU group. By 6 months, the groups were not significantly different.

Symptoms and Functioning

Repeated measures analysis with one grouping factor (BE-ACTIV vs TAU) and one repeated factor (baseline, treatment, 3- and 6-month follow-up) was used to analyze outcomes for the GDS scale and the COOP charts. The first step was to address the null hypothesis of no interaction between treatment and time. If no significant interaction was found, we tested the main effects for treatment and time. The Tukey-Kramer method for repeated measures was used to perform all pairwise comparisons. Pooling the interaction term with the error term was considered if doing so resulted in a better fitting model, as determined by the likelihood ratio (LR) test for the fit of the overall model. In all analyses, study participants were treated as nested within facility.

Table 2 shows summary statistics for measures across all waves. For GDS data, the interaction between time and treatment was not significant ($p = .948$). Removing this interaction term from the model resulted in a slightly better fitting model based on the LR test ($\chi^2 = 103.62$, $DF = 9$, $p < .001$; vs $\chi^2 = 101.52$, $DF = 9$, $p < .001$); a new model was tested in which the only effects were time ($p < .001$) and treatment ($p = .013$). In pairwise comparisons, baseline GDS differed significantly from posttreatment ($p < .001$), 3-month posttreatment ($p < .001$), and 6-month posttreatment ($p < .001$).

For the "daily activities" COOP item, the interaction between time and treatment was not significant ($p = .320$). Removing this interaction term resulted in a slightly better fitting model based on the LR test ($\chi^2 = 18.16$, $DF = 1$, $p < .001$; vs $\chi^2 = 17.43$, $DF = 1$, $p < .001$); a new model was tested in which the only effects were time ($p = .053$) and treatment ($p = .350$). None of the pairwise comparisons of time points were significant.

For the "social functioning" COOP item, the interaction between time and treatment was not significant ($p = .692$). Removing this interaction term resulted in a slightly better fitting model in terms of the LR test ($\chi^2 = 21.51$, $DF = 1$, $p < .001$; vs $\chi^2 = 20.77$, $DF = 1$, $p < .001$); a new model was tested in which the only effects were time ($p = .004$) and treatment ($p = .104$). In pairwise comparisons, baseline differed significantly from posttreatment ($p = .007$).

Table 1. Posttreatment Intent-to-Treat Diagnostic Outcomes

Group		Posttreatment outcome (intent-to-treat)			
		No change	Improved	Remitted	Worse
Control	Count	22	11	6	1
	% within group	55.0%	27.5%	15.0%	2.5%
Treatment	Count	18	4	19	1
	% within group	42.9%	9.5%	45.2%	2.4%
Total	Count	40	15	25	2
	% within group	48.8%	18.3%	30.5%	2.4%

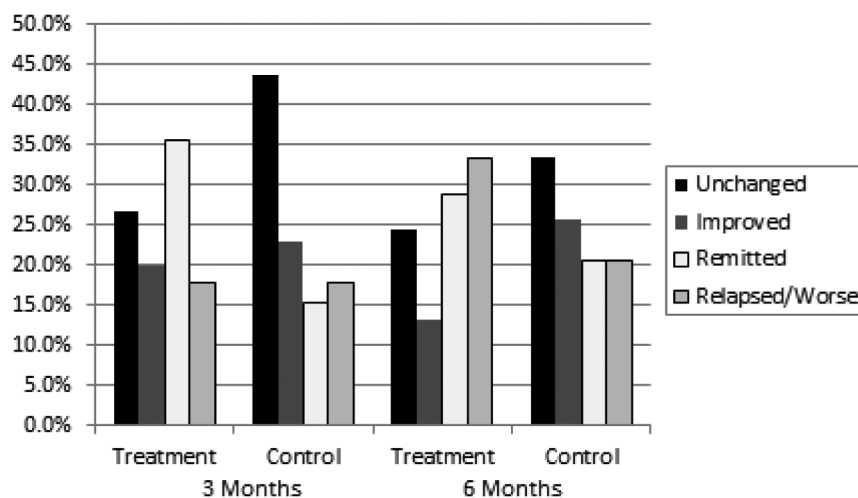


Figure 2. Intent-to-treat diagnostic recovery results for 3- and 6-month posttreatment.

Table 2. Outcome Variables at Baseline, Posttreatment, and Follow-up

Group	Time	GDS		COOP daily activities		COOP social function	
		N	Mean \pm SD	N	Mean \pm SD	N	Mean \pm SD
Treatment	Baseline	42	17.6 \pm 4.3	41	3.1 \pm 1.3	41	3.0 \pm 1.5
	Posttreatment	30	12.2 \pm 6.4	23	2.6 \pm 1.3	23	2.5 \pm 1.3
	3 months	31	13.0 \pm 5.9	31	2.7 \pm 1.2	31	2.9 \pm 1.3
	6 months	28	13.1 \pm 5.5	28	2.9 \pm 1.1	28	2.7 \pm 1.3
Control	Baseline	40	19.6 \pm 4.3	40	3.3 \pm 1.2	40	3.6 \pm 1.4
	Posttreatment	27	14.6 \pm 5.6	26	2.8 \pm 1.1	26	2.6 \pm 1.4
	3 months	23	16.1 \pm 6.3	22	3.2 \pm 1.3	22	3.3 \pm 1.4
	6 months	23	15.1 \pm 6.3	23	2.6 \pm 1.3	23	2.8 \pm 1.3

Notes. GDS = Geriatric Depression Scale; SD = standard deviation.

Treatment Integrity

Thirty-eight of the 42 participants in the BE-ACTIV group completed at least one session of treatment, and for these 38, the mean number of sessions was 7.23 ($SD = 3.42$); 24 participants (63.2%) stayed in the treatment through the end of the final session (Session 10). Most of the treatment withdrawals occurred between the first and second session. The modal number of sessions completed was 10, and 15 participants, or 39.5%, completed all 10 sessions. Sessions ranged in length from 10 to 80 min, with a modal length of 30 min.

Staff facilitators were present at 42.1% of first, 25.9% of fifth, and 44.4% of final sessions. Nevertheless, staff collaborators appear to have been successful in assisting residents with planned activities: Except for Weeks 2 and 5, the mean proportions of planned activities completed for each week exceeded 60% and in each week except the first, fifth, and sixth, the modal completion rate was 100%. On average, there were 5–6 activities planned for each week after Session 3, and residents gradually completed more of these, starting with an average of 3.62 in the third week and ending with an average of 4.41 in their final week (SD over weeks ranged from 2.22 to 2.55). Activities were varied, ranging from participation in scheduled facility group activities to

in-room music, crafts, reading materials, or puzzles, to self-care activities such as manicures or haircuts.

Results for therapist adherence (as rated by the first author based on session audio recordings) showed that session-specific mean adherence percentages ranged from 86% to 95%, with modal adherence at 100% for all sessions. Means for session quality ratings ranged from 5.5 to 5.8 (out of 6). Overall, the mean percent adherence rating was 84.47 ($SD = 26.22$), and the mean quality rating was 5.64 ($SD = 0.35$).

Resident and Staff Satisfaction

Mean resident satisfaction was 23.96 ($SD = 4.38$) out of a possible 31 points. Most residents (90.3%) reported they would recommend BE-ACTIV to a friend; 85.4% reported they had experienced increased activity, and 87.1% reported they had experienced improved mood. Staff reported a mean satisfaction score of 24.86 out 32 ($SD = 4.22$). Staff did not report spending more time with the residents than they had before the intervention, but 86.4% reported improvement in their relationships with the residents. Further, 90.9% of staff participants reported at least moderate satisfaction with the outcomes and 72.7% reported that they were “highly satisfied” with BE-ACTIV overall.

DISCUSSION

This paper presents the primary outcomes of a cluster randomized controlled trial of BE-ACTIV, a hybrid behavioral intervention for depression in nursing home residents, the largest such trial in the United States during the past decade. As with many clinical trials for depression treatments, the results suggest a mixed picture regarding the effectiveness of the intervention. BE-ACTIV resulted in better diagnostic recovery than TAU, based on clinical interviews performed by a clinician blinded to condition and using stringent intent-to-treat criteria. Treated participants were more likely than those in TAU to have a full remission at posttreatment and 3-month follow-up. For depressive symptoms and functional outcomes, however, both groups improved in similar trajectories.

The fact that there was significant improvement in self-reported depression and functional status in both groups suggests the possibility that the added attention component of our TAU condition may have helped improve mood and functioning. A recent meta-analysis of interventions in nursing homes suggested that interventions compared with active control conditions produced much smaller effect sizes (Cody & Drysdale, 2013). Previous research also suggests high persistence of depressed mood over time in the absence of an active treatment other than antidepressants (e.g., Raue et al., 2003; Smalbrugge et al., 2006). Although there are no directly comparable data in the literature to suggest the “natural history” of self-reported depressive symptoms in long-term care residents, our data appear to represent greater improvement than previous persistence data would suggest, which might be attributable to attention. Our diagnostic recovery findings suggest that BE-ACTIV can further aid in improvement by moving more patients from partial improvement to full remission, although we cannot rule out the possibility that this superiority is also due to added attention from more therapist contact in the BE-ACTIV group.

The BE-ACTIV and TAU groups differed at baseline on two important variables: depressive diagnosis and use of antidepressants. Post hoc analyses suggested that this difference did not provide an advantage for the BE-ACTIV group, which had proportionally fewer individuals with major depression. The antidepressant advantage should have been in favor of the TAU group, who had significantly more days on antidepressants. Thus, it seems unlikely that these group differences would alter the conclusion of superior remission following BE-ACTIV.

Participants who completed BE-ACTIV maintained their advantage 3-month posttreatment, but improvement in both groups leveled off after 3 months and, at 6-month posttreatment, the BE-ACTIV group no longer had an advantage in diagnostic recovery. For both groups, then, any therapeutic gain from the added attention of the research was short lived. This suggests that implementing effective interventions for depression in nursing home requires ongoing monitoring and attention to relapse prevention.

As previous research would suggest (Gaboda et al., 2011; Weintraub et al., 2002), the majority of participants in this study were taking antidepressants, for an average of 9 months, but still could be diagnosed with depressive disorders. This finding points to the critical need to determine the efficacy of nonpharmacologic approaches with this population. Posttreatment, 57.5% of the TAU group was still unimproved diagnostically, as was 45.3% of the BE-ACTIV treatment group. Thus, depression in this population appears to be quite treatment resistant. Research suggests that antidepressant therapy in nursing homes typically does not adhere to evidence-based practice (e.g., Shah et al., 2012; Weintraub et al., 2002), which may contribute to this problem. Our data suggest that BE-ACTIV has the potential to augment antidepressant treatment by encouraging diagnostic remission in a larger number of individuals. Research is needed that examines the comparative efficacy of psychosocial and antidepressant therapies among nursing home residents; because of the high prevalence of antidepressants in nursing homes, we do not know how effective an intervention like BE-ACTIV might be in the absence of an antidepressant.

The strength of our study design was our combined efficacy/effectiveness approach, with broad inclusion criteria so that our sample is representative of typical nursing home residents with respect to medical comorbidity, and with feasibility and implementation issues addressed throughout treatment development and testing. Using this approach produces a treatment that is more easily translatable, and our data suggest that BE-ACTIV can be implemented in long-term care facilities by mental health consultants with training comparable with our doctoral student therapists in this trial. Our treatment integrity analyses suggest that BE-ACTIV can be delivered by MA level psychology trainees under supervision, although we did not have an external evaluator. Activity staff ability to attend therapy sessions as called for in the manual was limited, but staff members carried out the majority of planned activities with residents. Residents and staff members reported general satisfaction with BE-ACTIV and perceived improvement in resident mood.

The broad inclusion criteria for our trial resulted in greater heterogeneity in our sample with regard to depressive diagnosis, medical comorbidity, and cognitive impairment than one usually finds in clinical trials. It is precisely the complex intersection of medical morbidity, cognitive impairment, and mental health problems that makes this long-term care population so difficult to treat, and any meaningful advance in depression treatment must address this complexity. Unfortunately, these complexities also posed significant barriers to participant recruitment, and consequently our sample size was smaller than our power analyses suggested was needed. Our choice of clustered randomization, while appropriate given the differences among facilities, also reduced our power and increased the difficulty of recruitment and the cost of

completing the trial. The combination of low power and high heterogeneity may have contributed to our lack of group by time differences in functioning measures. These issues may also have contributed to differences between our sample and the larger nursing home population with respect to age and disability, although these differences also could reflect the nature of the depressed individuals who were included as compared with nondepressed individuals in the broader sample. The fact that initial interviews were completed by a study author not blinded to condition also could have in some way contributed to bias in sample inclusion or pretreatment group differences. Another limitation of the study design is the fact that social support and coexisting anxiety disorders, both possible moderators of treatment success, were not assessed. The lack of an independent evaluator of treatment adherence and failure to control for differences in contact time between groups are also limitations. One final limitation of this study is regional bias. The region from which our data were collected is less ethnically diverse than metropolitan areas on the east or west coasts of the United States, although it may be representative of the midwestern regions. Corporate nursing home cultures may also differ by region, and eight of the facilities who participated were from a single corporation.

Conducting high quality, controlled research in nursing homes is a challenging enterprise because of the heterogeneity of the clinical population, differences among facilities, and cost of conducting research in numerous facilities that are geographically dispersed. Despite this difficulty, numerous small trials have suggested that psychosocial treatments, especially those involving behavioral activity and/or pleasant activities, can lead to improved depression (e.g., Cody & Drysdale, 2013; Hyer et al., 2005). The consensus of these trials and our results lend support to the conclusion that high quality mental health care should include individualized treatment that focuses on activation. Whereas our results suggest the possibility that just providing added attention can improve mood and functioning, full remission was more likely with BE-ACTIV. BE-ACTIV provides a model for a hybrid approach to depression treatment that is at least partially reimbursable under Medicare Part B, is structured, collaborative with and well accepted by staff, and time limited. Although there is still much that remains to be studied regarding comparative efficacy with antidepressants, mechanisms of effect, moderators of effect (see also Cody & Drysdale, 2013), impact on quality of life and functional outcomes, and barriers to maintaining treatment effects, the results presented here provide good evidence that BE-ACTIV can be an effective tool for treating depression in nursing homes.

SUPPLEMENTARY MATERIAL

Supplementary material can be found at: <http://psychogerontology.oxfordjournals.org/>

FUNDING

This work was supported by the National Institute of Mental Health (1 R01 MH074865).

ACKNOWLEDGMENTS

The authors wish to thank Linda Teri and Joel Streim for their support and sage advice throughout the process of developing and implementing this project. Thanks go also to research analysts Martha Sanders and Jesse Bradberry, and therapists Jim Rodgers, Irene Kostiwa, Lauren Hess, Shruti Shah, Brittney Getz, and Brian Ludwin. Finally, the authors wish to express their appreciation to the many nursing home staff members who provided support for this project.

CORRESPONDENCE

Correspondence should be addressed to Suzanne Meeks, PhD, Department of Psychological and Brain Sciences, University of Louisville, Louisville, KY 40292. E-mail: smeeks@louisville.edu.

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