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## Treatment Fidelity Evidence for BE-ACTIV – a Behavioral Intervention for Depression in Nursing Homes

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### Abstract

**Objectives:** Evidence-based depression therapies are difficult to implement in nursing homes. We present data for BE-ACTIV, a 10-week depression treatment designed for implementation in nursing homes, to address questions of treatment fidelity (delivery, receipt, and enactment) in that context.

**Method:** Participants were 41 patients from 13 nursing homes in the treatment arm of a clinical trial, treated by graduate student therapists. Therapists and their supervisor rated their audio-recorded sessions for adherence to treatment protocol and session quality.

**Results:** Delivery of core program elements averaged from 80–94% across all sessions; mean quality was 5.6 (SD 0.61) out of 6 points. Delivery of core components to nursing home activities staff who collaborated in the treatment was similarly high. Patients received an average of 7.32 sessions (SD 3.39); 17 completed 10 sessions. The theoretical basis of BE-ACTIV is behavioral activation; therapist-client dyads planned new pleasant events weekly, from a mean of 3.66 (SD 1.35) after the first session to a mean of between 5 and 6 activities a week across sessions 6–9, with a similar progression in percent activities completed. Activities enactment was significantly related to the likelihood of remission at post-treatment, and of maintaining improvement at 3-month follow-up. Treatment receipt and enactment were also related to improved mood from baseline to 3 months.

**Conclusion:** Results demonstrate delivery, receipt, and successful enactment of BE-ACTIV core components in diverse nursing homes and patients, and support the theoretical premise of the intervention. These findings support further implementation work for the BE-ACTIV intervention.

### Keywords

Depression; Intervention; Treatment Fidelity; Nursing Homes

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Depression affects up to 50% of the 1.4 million older adults in nursing homes (Centers for Disease Control, 2014; Gaboda, Lucas, Siegel, Kalay, & Crystal, 2011; Grabowski, Aschbrenner, Rome, & Bartels, 2010). Depression in this population is associated with poorer cognition, functional capacity, and health, and greater pain (Katz & Parmelee, 1997), use of more nursing time (Fries et al., 1993), suicidality (Reynolds et al., 1998), and mortality (Rovner et al., 1991). Depression care for nursing home residents is often lacking, inadequate, or inappropriate (Grabowski et al., 2010; Office of the Inspector General, 2001; Ulbricht, Rothschild, Hunnicutt, & Lapane, 2017). The most common intervention for depression in nursing homes is antidepressant medication (Arthur, Matthews, Jagger, & Lindsay, 2002; Gaboda et al., 2011). Although they can be effective for older adults (Boyce et al., 2012; Kok & Reynolds, 2017), antidepressants show poorer responses for frail patients (Bump et al., 1997; Kok & Reynolds, 2017; Little et al., 1998), may fail to mitigate bereavement (Reynolds et al., 1999) or eliminate hopelessness (Szanto et al., 1998), and have a greater risk of side effects in frail elders (American Geriatrics Society, 2012; Thakur & Blazer, 2008). Psychotherapy for depression is effective with older adults (Kok & Reynolds, 2017; Cuipers et al., 2014), including those with cognitive impairment (Orgeta, Qazi, Spector, & Orrell, 2014) and several models have been tested in nursing homes (see Cody & Drysdale, 2013; Snowden, Sato, & Roy-Byrne, 2003, for reviews), including the model that is the focus of this study (Meeks, Van Haitma, Schoenbachler, & Looney, 2015; Travers, 2017). Nevertheless, few nursing home residents receive psychotherapy; one reason evidence-based treatments are not adopted may be barriers that are specific to implementation in nursing homes (Bartels, Moak, & Dums, 2002; Office of the Inspector General, 1996; Reichman et al., 1998).

The evidence-practice gap found in nursing homes is not unique (Westfall et al., 2007); focus on internal validity in clinical trials has limited the generalizability of scientific innovation of all kinds. As a consequence, there is a growing interest in studying best methods for disseminating, adapting, and implementing scientific innovation in “real world” clinical settings. Rogers’ Diffusion of Innovation theory (2003) explains decisions to adopt innovations in five stages: knowledge, persuasion, decision, implementation, and confirmation (maintenance). The decision to adopt a practice is influenced by the acceptability, appropriateness, and feasibility of that practice in a particular setting (Proctor & Brownson, 2012). Rogers (2003) identified five attributes of an intervention that facilitate adoption: effectiveness, fit with the setting, visibility of outcomes, trialability, or the degree to which it can be adapted, and complexity. Planning and developing interventions with attention to feasibility in the design phase, early partnership with stakeholders, developing an understanding of the setting, and accumulation of evidence relevant to practice facilitate implementation (Gaglio & Glasgow, 2012; Rabin & Brownson, 2012). These attributes facilitate the most commonly measured implementation outcomes from the RE-AIM framework (RE-AIM.org, 2017): Reach, or the number of people who receive the intervention, effectiveness, adoption by the target providers, implementation with fidelity, and maintenance of the practice. The purpose of the current paper was to examine characteristics of a behavioral intervention for depression, designed for use in nursing homes, that support its implementation in nursing home practice, thus furthering the goal of diminishing the evidence-practice gap for treating depression in nursing homes.

## Description of the Intervention with Respect to Rogers' Theory

### Theoretical and Empirical Grounding of the Intervention

BE-ACTIV is a 10-week psychotherapy grounded in the theoretical work of Lewinsohn and colleagues (Lewinsohn, Hoberman, Teri, & Hautzinger, 1985) and evidence of the importance of positive affect in depression (Meeks & Depp, 2003). It shares a pleasant events or behavioral activation focus with many depression treatments supported by research (e.g., Gitlin, Roth, & Huang, 2014; Teri, Logsdon, Uomoto, & McCurry, 1997; Van Haitsma, et al., 2015); part of the evidence for its efficacy comes from this commonality with other evidence-based interventions that use cognitive-behavioral techniques to increase activation (see the following reviews: Cody & Drysdale, 2013; Barucha, Dew, Miller, Borson, & Reynolds, 2006; Snowden et al., 2003). Cognitive-behavioral, behavioral activation, problem-solving therapy, Beat the Blues (Gitlin et al., 2014), and pleasant-events treatments all include modules or emphasis on increasing patient activity levels through planning pleasant events or other activities. This is also a component of exercise therapies (e.g., Lok, Lok, & Canbaz, 2017), which show promise in nursing homes.

### Attention to Feasibility, Early Stakeholder Participation

Meeks and colleagues developed the BE- ACTIV treatment manual in a collaborative study with nursing home staff, designing the intervention to fit in the nursing home environment. The result was a hybrid treatment model in which the mental health therapist (MHT) has one-to-one weekly sessions with the patient, works with staff to support and facilitate pleasant events, and invites staff to participate in selected therapy sessions (Meeks, Teri, Van Haitsma, & Looney, 2006; Meeks et al., 2008). In this model, the MHT can receive reimbursement under Medicare Part B, making the treatment feasible for private providers.

### Evidence for Feasibility and Effectiveness

The research team tested the intervention in a feasibility trial in six nursing homes, collecting feedback from nursing home staff about acceptability and burden, and demonstrating promise of efficacy (Meeks et al., 2008). We then conducted a hybrid efficacy-effectiveness RCT in 23 nursing homes. Broad inclusion criteria created a representative sample of nursing home residents (see Green & Nasser, 2012), including those with significant sensory, cognitive, and physical impairments to improve the reach of the intervention. The outcome of this trial showed that patients treated with BE-ACTIV improved more rapidly and achieved more complete remissions than patients who received treatment as usual (Meeks et al., 2015).

### Focus of the Present Study: Treatment Fidelity

In the clinical trial of BE-ACTIV cited above, we collected treatment fidelity data and analyzed these data for the current paper. According to Borelli (2011), treatment fidelity should be assessed across study design, provider training, and treatment delivery, receipt, and enactment. We focus on treatment delivery, receipt, and enactment, as assessed during the previously published clinical trial. *Delivery* is whether providers maintain treatment-specific skills after training, deliver the core elements of the treatment as specified in the

treatment manual, and do not deliver components of other treatments. *Receipt* is whether recipients of the treatment understand the principles of the treatment and can respond appropriately; dose is a component of receipt indicating whether patients received the intervention in sufficient quantity to make an impact. *Enactment* is whether recipients continue to carry out core skills or behaviors in appropriate settings (i.e., outside of the therapy room). All aspects of fidelity rely on the treatment having a theoretical basis that defines the hypothesized mechanisms of action and the core elements of the intervention that produce those mechanisms. The behavioral theory of depression underlying BE-ACTIV predicts that increasing activation by improving access to preferred pleasant events will result in increased positive affect (Lewinsohn et al., 1985; Meeks & Depp, 2003). Figure 1 depicts a simplified model of this theory specifying the core elements of the treatment.

The research questions for this study included questions of delivery, receipt, and enactment listed below. We also wanted to know whether treatment fidelity variables related to treatment outcomes.

1. **Delivery:** Were the core elements of BE-ACTIV delivered as expected in the treatment manual? These include giving the rationale, identifying and scheduling pleasant events, reinforcing residents for effort, identifying and problem-solving barriers, interacting with staff members, and reinforcing staff for effort.
2. **Receipt:** did participants receive 5 or more sessions in which the therapist and client assessed and planned pleasant events? Did staff members participate in sessions?
3. **Enactment:** Did the clients successfully enact increasing numbers of pleasant events over the weeks of therapy? What were the most commonly enacted pleasant events? Did staff members support pleasant events? What barriers did residents and staff encounter in enacting pleasant events?
4. **Fidelity and Outcome:** Were receipt or enactment of BE-ACTIV core elements of pleasant events and staff participation related to diagnostic recovery, depressive symptoms, or positive affect?

## Method

### Design

The data we analyzed came from a two-group, cluster randomized clinical trial of the intervention. Randomization was by nursing home to prevent contamination by staff education. The principal investigator (SM) provided a free training session for nursing home activities staff at the intervention facilities, providing information about depression, the rationale for the BE-ACTIV intervention, and their role in implementing pleasant events with the participating residents. Nursing home residents in the intervention group began weekly sessions with the mental health therapists (MHTs) after a two-week baseline observation period. We have published the effectiveness outcomes of this trial elsewhere (Meeks et al., 2015). We collected fidelity data weekly during the 10-weeks of treatment delivery.

## Measures

### Resident Mental Health Data

We administered the Mini Mental Status Exam (MMSE) (Folstein, Folstein, & McHugh, 1975), one of the most widely used mental status examinations (Tombaugh & McIntyre, 1992), to assess cognitive status at baseline. The MMSE consists of 11 items that cover orientation, registration, attention/calculation, recall, and language function. Scores range from 0–30. We used the Geriatric Depression Scale (GDS) (Brink et al., 1982), a 30-item, self-report depression screening scale developed for use with older adults to assess depression severity at baseline, post-treatment, and 3- and 6-month follow-up assessments. Scores on the GDS range from 0 to 30, with scores 11 or higher indicating clinically significant depression. The psychometric properties of the scale are well established for medical settings (e.g., Koenig et al., 1988; Leshner, 1986). McGivney and colleagues (1994) found 84% sensitivity and 91% specificity rates for detecting clinical depression using a GDS cutting score of 11 in cognitively impaired patients with MMSE scores above 14. Internal consistency for this sample was .70.

Participants rated their mood weekly using a modification of the Philadelphia Geriatric Center Positive and Negative Affect Rating Scale (ARS; Lawton, et al., 1992). This scale contains 10-items, five for positive affect (energetic, interested, warmhearted, happy, and content) and negative affect (depressed, sad, worried, annoyed, irritated). Items are rated from 1 (not at all) to 5 (very strongly) in response to the probe “how are you feeling right now?” An examiner reads the items aloud and presents them visually at the same time (Lawton, et al., 1996). Research staff collected weekly mood ratings during baseline, and MHTs collected them during intervention sessions, and for two weeks at each follow-up.

The primary resident outcome for the clinical trial was diagnostic recovery. We used the mood disorders section of the SCID-IV, Non-Patient Research Version (First et al., 2002) to establish research diagnoses. The first author completed the pre-treatment interviews, and a research psychiatrist who was blind to condition completed the post-treatment and follow-up interviews. Both interviewers had completed recommended training for the SCID (Ventura, Liberman, Green, Shaner, & Mintz, 1998) and achieved diagnostic reliability of .75 or better (kappas or intra-class correlations) on practice videotapes before conducting study interviews. The two interviewers reached consensus for the final diagnoses. To code diagnostic recovery, two raters coded all cases independently. Kappa between the two raters was .84 for post-treatment outcomes,  $p < .001$  ( $N=82$ ). Diagnostic recovery codes at post treatment 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 (MDE) to MDE in partial remission, or from MDE to a lesser form of depression (e.g., Depression NOS), and who still had 2 or more depressive symptoms coded on the SCID, were coded as “improved”. Those who could not be given a diagnosis because they had no symptoms at post-treatment, or who were diagnosed as MDE in full remission, or 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, participants who did not complete a post-treatment 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 had not fully remitted. In intent-to-treat analyses, when there were data missing, the participant was coded as unchanged from the prior assessment.

### Treatment Fidelity Variables

Fidelity variables came from four sources of information: from PI ratings of audio recorded treatment sessions, from MHT self-ratings of each treatment sessions, from MHT-maintained therapy records, and from MHT-administered assessment of the clients’ pleasant events participation.

**Delivery to Patients.**—We used scales adapted from those by Teri and colleagues (1997) and our pilot work (Meeks et al., 2008) to assess whether MHTs adhered to the treatment manual. The PI and the MHT rated each session using these scales to collect our primary measures of treatment delivery to the clients. The scales differed slightly for each session based on content of the sessions; items were rated 1 (no) or 2 (yes) to reflect whether the therapist accomplished tasks from the manual. Table 1 shows the items and their relevant sessions. Core components examined (see Figure 1) were providing the rationale, identifying and scheduling pleasant events, reinforcing residents for effort, and identifying and problem-solving barriers –shown in bold at the top of Table 1. For each session there were also three quality ratings, from 0 (not at all) to 2 (completely), regarding whether the therapist responded to the client’s needs and avoided irrelevant techniques, and the overall quality of the session. Thus the scales yielded two scores for each session: an adherence score which counted the number of 1’s for the adherence items, and a quality score summing the ratings for the three quality items. The adherence items were also summed across sessions to yield an overall adherence score for each core component.

**Delivery to Staff.**—The treatment manual included the expectations that MHTs have weekly contact with an activity staff member, who then would be responsible for assisting the residents to carry out planned activities. The MHT was to discuss any barriers to activity implementation, help the activities staff understand how characteristics of depression and dementia might have been barriers to participation, and discuss how to handle those barriers if present. MHTs rated their weekly contacts with the designated staff member working with the target client. Ratings included whether the meeting occurred, whether the MHT reviewed the session agenda with the staff member or reinforced the staff member for effort, and what they discussed during their meeting (barriers, resources needed, information on depression/dementia/behavior management, or family issues (see Table 2 for a list of items). The core elements for staff receipt were reinforcing the staff for effort, discussing barriers, and providing a rationale based on information regarding depression.



**Receipt.**—MHTs completed weekly session logs that indicated time and date of sessions, length of sessions, whether or not a family member or staff member was present, number of activities planned for the following week, whether the client had completed pleasant activities for the previous week, and any barriers identified that led to activities not being completed. We used the number of sessions each participant completed to examine the dose of treatment received. Other receipt variables were the number of activities planned, and whether an activities staff member attended sessions; the manual suggests that an activity staff member should attend sessions 1, 5, and 10.

**Enactment.**—The weekly session logs described above provided the counts of planned and completed activities each week, our primary enactment variable, and problems encountered that prevented activity completion. For planning appropriately tailored pleasant events, the MHTs administered the Pleasant Events Schedule-Nursing Home Version (PES-NH) during each of sessions 1–9. The initial version (used in session 1) assesses former activities that the client has found pleasant, asks the client to rate them in terms of pleasantness, availability, and frequency of these activities in the present. The follow-up version, used in subsequent sessions, asks only about events the client had rated as pleasant, asking whether they occurred in the previous week, and how pleasant they were if so. The PES-NH is an adaptation of the PES-AD, a version developed by Logsdon and Teri (1997) for use with caregivers of persons with dementia. The PES-NH was developed to identify pleasant events that are available and/or feasible in the restricted nursing home environment (Meeks, Shah, & Ramsey, 2009). It includes 30 items and yields a count of pleasant activities occurring each week, and a rating of pleasantness of those activities.

As an indicator of staff enactment, MHTs also estimated weekly the number of minutes the designated activities staff member had spent with the participating resident in that week (including time in group activities led by the staff member). This estimate was based on staff member report when available plus weekly records of activities kept by all activities staff, and MHT knowledge about which activities the client had attended and other staff contacts reported by the resident as part of their review of weekly activities.

## Participants

Data collection and patient consent methods were reviewed and approved by the University of Louisville Institutional Review Board. Forty-two residents from 13 nursing homes randomized to the intervention arm of the clinical trial agreed to participate; 41 received at least one treatment session and constitute the sample for the current study. All had diagnoses of a depressive disorder – 51.2% had a diagnosis of major depressive episode, the rest had other DSM-IV depression diagnoses including minor depression (22.0%), mood disorder secondary to a general medical condition (9.8%), or dysthymic disorder (7.3%). Resident participants ranged in age from 53 to 100, with a mean age of 77.29 [standard deviation (SD) =12.22]. They were 65.9% women and 90.2% white, non-Hispanic, 9.8% African American. They had a mean education of 12.50 years (SD=3.51). They were all in long-term care, with a modal length of stay of 12 months; half had been in long-term care for 21 months or more. At baseline, participants had mean GDS scores of 17.60 (SD=4.33) and

mean MMSE scores of 22.07 (SD=4.84). The ARS positive affect mean was 12.00 (SD=3.33), and negative affect mean was 11.77 (SD=4.56).

Thirty-four staff members out of 37 who received the BE-ACTIV training module consented to supply data about themselves. They represented 12 of the 13 treatment nursing homes. These individuals had a mean age of 39.64 (SD=12.46), and had worked in long-term care settings a mean of 10.13 years (SD=6.51). Most of those who participated in the training were either activity directors (32.4%) or activity assistants (54.1%); three (8.1%) were other staff members who participated in the trainings out of interest but who did not participate in delivering the pleasant events during the intervention phase. The majority (89.2%) worked full time. Of the three people who did not provide personal information, one was an activity director; the others were staff members who were interested in the training but who did not participate in the intervention.

The mental health therapists (MHTs) for the clinical trial were four clinical psychology doctoral students being trained in the first author's research lab; they participated as paid research staff. All had completed at least one year of clinical training prior to involvement in the study; all were women. The MHTs all completed a training seminar and practicum on the intervention prior to beginning their work on the study. The Principal Investigator, a licensed clinical psychologist, supervised each MHT in the practicum, reviewing and rating audio-recorded sessions for adherence to the treatment manual, and discussing the sessions in weekly group supervision sessions with the MHTs. All MHTs met a criterion of 80% adherence with treatment manual expectations across 10 treatment sessions with at least one clinical case in a nursing facility before joining the study.

## Results

### Delivery

**Delivery of Core Elements in Therapy Sessions**—MHTs' completion of session self-ratings was as high as 100% for sessions 2–5, and near 100% for other sessions. The PI rated a comparable percentage of sessions, missing only sessions where the audio recorder failed to work. We calculated percent agreement between the PI and the MHTs on adherence ratings for every session. Mean overall session agreements (averaged across items within session) ranged from 87.7% for Session 1 to 94.3% for Session 10. The average agreement was 87.7%. Agreement (averaged across sessions) on the core components of intervention were as follows: providing the rationale, 88.4%, identifying pleasant events in the first session, 95.1%, reinforcing residents for effort, 92.0%, and identifying and problem-solving barriers, 91.2%. This level of agreement suggests that MHTs were able to recognize the degree to which they were delivering core components as expected in the manual.

Agreement on quality ratings was assessed with Intra-class Correlations (ICCs). The ICC between MHTs and the PI across all sessions was .51,  $p = .02$ , which, although significantly different from chance, suggests that the PI and the MHTs differed somewhat on their assessments of the overall quality of sessions. We looked at the mean percent fidelity per session ratings by the PI vs. the MHTs, and these means were quite close: 83.17% (SD=4.74) as rated by the PI vs. 83.84 (SD=6.92) as rated by the MHT. Similarly, the mean quality ratings per session were nearly identical: 5.64 (SD=.35) vs. 5.64 (SD = .58),



respectively. These findings suggest that a leniency bias in therapist self-ratings as compared to those of their supervisor was not an explanation of differences among the ratings.

Table 1 shows PI ratings regarding overall MHT adherence to session expectations, and delivery of the core components. This table shows that MHTs were very consistent in providing the rationale for treatment (88.8% of sessions overall, but 97.6% in the first session), assessing and reviewing pleasant events (100% and 99.4%, respectively), and reinforcing the client for effort (91.4%). They were somewhat less consistent in discussing barriers to completing pleasant events (87.4% overall). Mean percent compliance with session expectations was high, 93.1%. PI ratings of quality of sessions ranged from 5.44 out of a possible 6 points ( $SD=.91$ ) for session 4 to 5.83 ( $SD=.45$ ) for session 3, with a mean quality rating of 5.64 ( $SD=3.5$ ) across all sessions and therapists. We compared therapists on these variables using one-way analyses of variance, and there were no significant differences among the four therapists in mean quality or adherence ratings averaged across all sessions or for individual sessions.

**Delivery of Core Elements to Staff**—Despite difficulty of scheduling a staff member in sessions (see Receipt, below), MHTs were able to make contact with staff members outside of the formal session during most weeks, with face-to-face meetings occurring in 84.6% of the first three weeks of treatment, with later weeks ranging from 87.1%, to 53.6%. If the meeting did not occur, it was nearly always because the MHT was unable to locate the staff members, or the staff members were busy. The expectations for this contact included the key components of reinforcing staff for effort and discussing barriers. When meetings took place, reinforcing staff for effort was the most common topic, followed by discussing barriers, important core staff components of BE-ACTIV. Also common were giving the staff information about depression, discussing resources, and discussing maintenance of gains and care planning, especially during the latter weeks of treatment. Table 2 shows the content of meetings with staff.

## Receipt

Participants completed an average of 7.32 sessions ( $SD=3.39$ ); the modal completion was 10 sessions and 17 participants (41.46%) received 10 sessions. We reported attrition analyses with the clinical trial outcomes (Meeks, et al., 2015); the primary reason for discontinuing was a health event or death, and no other participant characteristics predicted discontinuation. Mean session length was 41.90 minutes ( $SD=14.56$ ). Session length varied based on participants' cognitive capacity, verbal engagement, and physical endurance, but the goal was to deliver the core components weekly. As is the case for most interventions delivered in nursing homes, sessions occurred wherever the MHT could find a private or semi-private space, or, if the participants was unwilling to move, in their rooms. The expectation from the BE-ACTIV manual was that an activity staff member would be present for sessions 1, 5, and 10. Staff members were present for 39.0% of first sessions, 24.1% of fifth sessions, and 44.8% of final sessions, suggesting that this expectation was difficult to meet.

## Pleasant Events Planning and Enactment

Figure 2 shows the mean number of events planned during each session (light bars) and the number carried out; these data come from therapist notes. The BE-ACTIV manual calls for planning at least three new events during the first session, and increasing the number planned each week thereafter. The results in Figure 2 show an average of 3.66 (SD=1.35) events planned in Session 1, and the number planned peaked between sessions 5 and 9 (Means = 5.44–6.11, SD= , 2.41–2.15, respectively), also as expected. Overall, the mean percent of planned activities completed ranged from a low of 65.3% (SD=20.8%) for Session 6 to a high of 80.6% (SD=17.9%) for Session 7.

Each week, MHTs recorded reasons that the planned pleasant activities did not occur. There was an overall mean of 4.21 (SD=2.69) barriers recorded per participant over all sessions. The most common resident-related reasons for non-occurrence were resident refusal (42, or 34.43% of all barriers), and resident health problems (37, or 30.33%). Modally at least one family obstacle was also encountered, and it was common for alternative activities to account for residents not participating in the planned activities, accounting for 22.95% of barriers. Resident refusal accounted for 66.67% and 60.0% of failures to enact events after the first and second weeks of treatment, respectively. By the last two weeks of treatment, resident refusal accounted for only 27.27% and 16.67% of failures to complete activities, respectively, suggesting that the focus on motivating participants through reinforcement and problem-solving other barriers was effective. Participation in alternative activities accounted for a greater proportion of the failures to complete planned activities in the latter weeks of treatment. MHTs reported no staff-related reasons for activities not occurring. These findings are consistent with successful participant activation as therapy progressed.

Residents' ratings of interesting activities on the Pleasant Events Schedule (PES) during Session 1 ranged from 9–30 activities, with a mean of 21.26 activities that they reported as potentially interesting (SD=4.72). Participants reported that about 10 PES activities occurred during each week of treatment, although there was variability among residents with standard deviations around 6. Note that these activities may have included the planned/carried out activities shown in Figure 2, but also included other things that happened to participants during the week. These statistics highlight the importance of tailoring both activities and expectations to the individual resident. Among the most common activities reported on the PES were watching television, being told they are loved, laughing, receiving visitors, and having preferred snacks. However, all of the activities listed on the PES occurred a mean of at least one time per week during the study, illustrating again the idiosyncratic nature of resident activity preferences.

The average time that the activity staff members who worked with the MHTs spent with the resident, which is shown in the last column of Table 2, was estimated weekly by the MHTs with input from staff members. This is an indicator of staff enactment if we assume that staff would need to spend more time with residents in order to help them carry out preferred activities. Activities staff member time with the participants increased from sessions 2–4 (average of 163.33 minutes per week) to later sessions (average of 190.33 for sessions 5–10), about 30 minutes per resident per week.

## Relationship of Receipt and Enactment with Outcomes

Table 3 shows the means and standard deviations of treatment receipt and enactment variables (number of sessions, activities planned, activities completed, and staff time with resident) by the main clinical trial outcome, diagnostic recovery, for the intent to treat sample. Asterisks in the table indicate significant group differences from one-way analyses of variance. At post-treatment and at the 3-month follow-up, the groups were significantly different in the number of activities planned,  $F(3,37) = 3.23, p = .027$  and  $F(3,37) = 3.06, p = .04$ , respectively. They also differed in number of activities completed,  $F(3,31) = 4.69, p = .008$  and  $F(3,31) = 5.33, p = .004$ , respectively for post-treatment and three month follow-up. At three months, participants who maintained recovery had completed significantly more treatment sessions,  $F(3,37) = 4.87, p = .006$ . There were no significant differences among the four groups at six month follow-up. We also conducted group comparisons for survivors only, recognizing that treatment receipt and enactment are going to be confounded with other factors leading to dropout in the intent-to-treat sample. The pattern of results was similar for the survivors-only analyses. In order to further examine the potential benefit of treatment dose and enactment variables on outcomes, and because the group sizes were quite unequal, we conducted paired comparisons using *t*-tests comparing those who were fully remitted at each assessment vs. all others; these *t*-tests are shown in Table 4. With the groups collapsed in this way, it is easier to see that patients who had remitted at post-treatment planned and completed more activities, and had more time with staff, than those who were not. Those who were remitted at the 3-month follow-up had more planned activities and more sessions completed than those who were not. The difference in number of sessions disappeared when only survivors were analyzed, confirming that sessions completed is confounded with completion of the study overall.

We computed Pearson's correlation coefficients of number of sessions, planned and completed activities, and staff time, with the secondary outcomes of positive and negative affect and Geriatric Depression Scale (GDS) scale scores at baseline, post-treatment, and 3 and 6 month follow-ups. Since mood scores were measured weekly, we averaged scores across the two baseline weeks, across sessions 5–10 of therapy, and across the two weeks at each follow-up. No fidelity measures were related to baseline GDS or baseline mood. Neither staff time nor number of sessions completed were related to mood or GDS, with the exception of 3-month follow-up GDS, which was significantly correlated with staff time,  $r(29) = -.41, p = .029$ . Planned and completed activities showed similar patterns of correlation with outcomes, although only completed activities were consistently significant, with post-treatment GDS ( $r(26) = -.46, p = .017$ ), 3-month GDS ( $r(26) = -.38, p = .054$ ), 6-month GDS ( $r(23) = -.46, p = .027$ ), weeks 5–10 therapy positive mood ( $r(30) = .55, p = .002$ ), and 3-month positive mood ( $r(25) = .54, p = .005$ ). There were no significant correlations with negative mood.

To look at change in depressive symptoms and positive mood from baseline to post-treatment, we conducted two hierarchical regression analyses with post-treatment scores on GDS and positive affect, respectively, as dependent variables, and the baseline values for the dependent variables were entered in the first step, followed by completed activities in the second step. Both of these equations yielded overall significant results,  $R = .52, p = .028$ ,

and  $R = .75$ ,  $p < .001$ , respectively, for GDS and positive affect. In each equation, the second step yielded a significant  $R^2$  change, .23 and .27, respectively, suggesting that the number of completed activities predicted post-treatment change in mood and depressive symptoms.

## Discussion

The purpose of this paper was to assess evidence that an effective treatment for depression in nursing homes was implemented with fidelity in its clinical trial, and to evaluate whether variables measuring receipt and enactment related to clinical trial outcomes. The question of whether a treatment can be implemented with fidelity in a “real world” clinical setting is crucial to diminishing the gap between research knowledge and widespread use. We know that although there are efficacious psychotherapies for treating late-life depression, such therapies are rarely used in the nursing home setting, where depression is prevalent. The BE-ACTIV intervention was designed for implementation, and fidelity measures were included among clinical trial measures. The results of those assessments are reported here.

We demonstrated good reliability between therapist and observers regarding whether therapists delivered core elements of the BE-ACTIV intervention. The core elements, according to the theoretical model underlying BE-ACTIV, are providing the treatment rationale, assessing and planning pleasant events, reinforcing the patient for effort, and problem-solving barriers to carrying out pleasant events. We demonstrated that the mental health therapists (MHTs) consistently delivered these components, and other elements prescribed in the treatment manual. Delivery of core components was particularly strong in earlier sessions, and, as expected, in the very last session, where reiteration of the rationale and individual reinforcement are used to solidify progress. We also demonstrated that the majority of patients received a strong dose of the treatment, modally all 10 sessions and on average about 7 sessions with an average length of about 42 minutes.

The key hypothesized mechanism for BE-ACTIV’s effect is pleasant events planning and enactment. Our data suggest that participants received pleasant event planning and, on average, planned the expected number of pleasant events, which increased according to the manual across the 10 sessions of therapy. The wide variety of activities planned and enacted reinforces a central tenet of BE-ACTIV, that activity planning should be individualized rather than delivering group or communal activities. The importance of individualized planning was underscored by the fact that the most common reason for not enacting a planned event was the resident’s refusal to participate. Participants’ activity refusal dropped across sessions, suggesting that the one-to-one sessions were effective for increasing patient motivation to engage, and/or better tailoring future planned events to the residents’ preferences. The significant relationships between activities enacted and the principal trial outcomes of diagnostic remission, improved mood, and reduced depressive symptoms supports the hypothesis that promoting increased pleasant events is indeed a core element of the treatment. The persistence of the relationship between activities and outcome at the 3-month follow-up but not at 6 months suggests that the participants’ activation continued or continued to have benefit for a few months, but that the effect was not maintained long term. The importance of personalization, and of the relationship between activities and positive mood, are consistent with the results of a study by Kolanowski and colleagues (Kolanowski,

Litaker, Buettner, Moeller, & Costa, 2011). Although the focus of their trial was behavioral problems in residents with dementia, the authors found an effect on positive mood that was strongest when activities were personalized.

Another core component of BE-ACTIV is staff collaboration. We demonstrated that MHTs involved activities personnel in the treatment. Although a frequent barrier was staff not being available for meetings with residents, the MHTs were able to communicate activity goals to staff members, staff members were able to enact the activities independently, and MHTs were able to reinforce staff members for their efforts. Successful staff engagement is consistent with the relatively high staff acceptance of and enthusiasm for the intervention that we have reported elsewhere (Meeks et al., 2015; Meeks et al., 2008). As a result, activities staff time with treated patients increased over the weeks of treatment. Increased staff time during treatment weeks was associated with remission from depression at post-treatment, and with mood at three months post-treatment, suggesting that participants benefitted from staff attention and that attention may have had some lasting effect on general mood even if it did not have the same relationship to diagnosis at the three-month follow-up. As shown in Table 3, participants who were worse or relapsed at three-month follow-up also had a high amount of staff time. It is possible that these residents generated more refusals to go to planned activities, leading to more staff interaction in attempts to persuade them to attend. Since this is a relatively small group of patients, it is difficult to draw a firm conclusion on this counter-intuitive result, but the result suggests the need to assess additional parameters of resident-staff interaction, including frequency, duration, and quality.

A major limitation of this demonstration of implementation fidelity is that the MHTs in this clinical trial were graduate students under the supervision of the study principal investigator. Each session was audio-recorded, rated, and discussed during weekly supervision, which likely heightened compliance with treatment manual expectations. Providers who are already in practice may be more reluctant to follow a treatment manual than trainees, and may therefore be less likely to deliver core elements with fidelity. Nevertheless, the clinical trial data demonstrate that delivery, receipt, and enactment in diverse nursing facilities is feasible and effective, and provides the ground work for future implementation studies.

Because BE-ACTIV was designed with the nursing home setting in mind, it may be easier to implement effectively in that environment than other evidence-based treatments for depression, and thus has promise for narrowing the evidence-practice gap for treating depression in nursing homes. We demonstrated that the core elements were delivered as expected in the manual, that patients received pleasant events planning and enacted events increasingly across the 10 weeks of treatment, and that staff involvement was an important component in delivery and enactment. Delivery of core elements was related to patient outcomes. We found that participation of staff was the most difficult element to deliver, consistent with a similar, smaller trial (Travers, 2017); asking staff members to find time to attend sessions appears often to be unreasonable. Nevertheless, weekly short conversations with staff were possible, and staff members increased their time with participating residents and assisted in carrying out planned activities. Our clinical experience suggests that reinforcing staff for effort is a key element of bringing about this assistance. Working with staff in this manner, we were successful in increasing participation in preferred pleasant

activities, and increased activation of this kind was related to mood and depression outcomes. Providers who work collaboratively with staff to increase access to pleasant events may deliver effective depression treatment in nursing homes. This conclusion is congruent with findings of other research groups (e.g., Hyer, Yeager, Hilton, & Sacks, 2009; Travers, 2017). Future research using pragmatic effectiveness and implementation trials are necessary to demonstrate whether the intervention can be disseminated to the multidisciplinary providers who typically deliver depression treatment in nursing homes. The intervention has the potential to help reduce medication burden on patients and improve depression outcomes.

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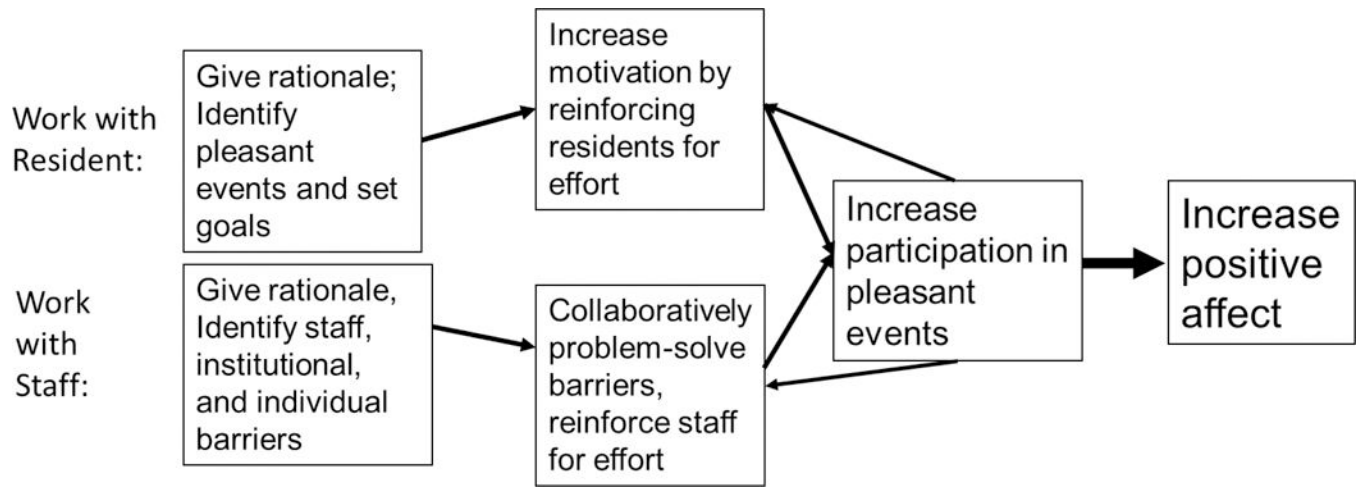
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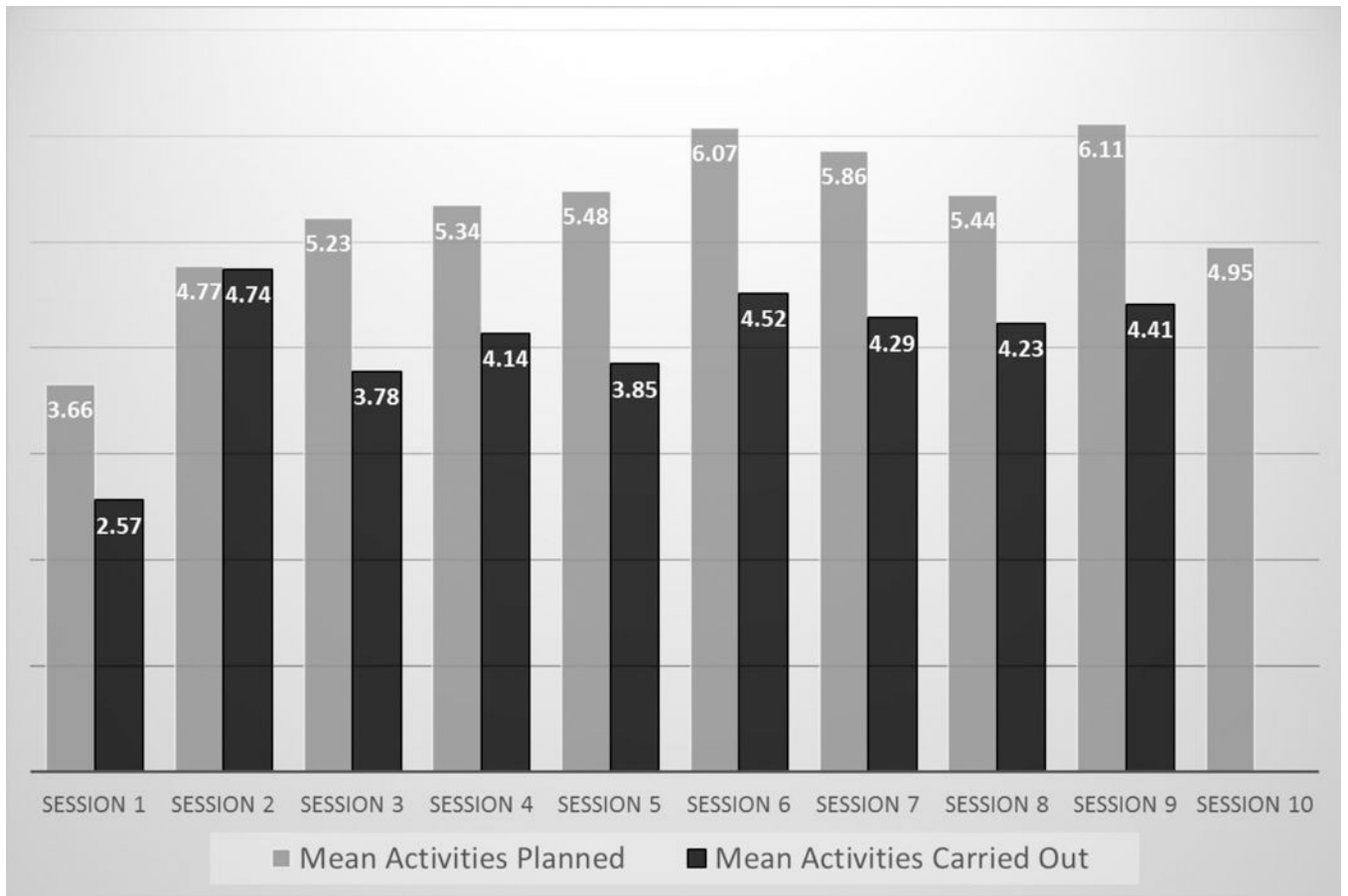
**Figure 1.**  
Simplified model of treatment core components.

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**Figure 2.**  
Planned versus completed activities across sessions.

Mental Health Therapist (MHT) *delivery* of treatment components to nursing home residents, as rated by project Principal Investigator after reviewing audio-recordings of sessions, shown in percent of sessions rated in which component was delivered.

**Table 1.**

Item	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Average All Weeks
<b>Rationale for Treatment Given</b>	97.6%	92.1%	80.5%	85.3%	87.5%	82.9%	85.3%	91.4%	88.6%	97.2%	88.8%
<b>Pleasant Events Scale Completed</b> <sup>1</sup>	100.0%	*	*	*	*	*	*	*	*	*	100.0%
<b>Reinforced Patient for Effort</b>	*	84.2%	82.9%	94.1%	100.0%	97.1%	87.9%	88.2%	91.4%	97.1%	91.4%
<b>Discussion of Barriers</b>	87.5%	89.5%	81.6%	88.2%	85.7%	82.9%	97.0%	82.4%	91.4%	*	87.4%
Session Occurred on Time	*	97.4%	100.0%	100.0%	97.2%	100.0%	97.1%	100.0%	100.0%	100.0%	99.1%
Review of Previous Week	*	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	97.1%	97.2%	99.4%
Review of Accomplishments	*	*	*	*	75.0%	*	*	*	*	*	75.0%
Focus on Observable Behavior	100.0%	100.0%	90.2%	100.0%	97.0%	100.0%	100.0%	100.0%	100.0%	*	98.6%
Discussion of Future	*	*	*	*	*	67.6%	78.8%	71.4%	94.3%	100.0%	82.4%
Average all items	96.3%	93.9%	89.2%	94.6%	91.8%	90.1%	92.3%	90.5%	94.7%	98.3%	91.3%

Note: Bolded items identify core components of BE-ACTIV. Table 2 shows staff-related core components.

\* Component not required/rated in this session.

<sup>1</sup>The Pleasant Events Scale (PES) was used every session, but the full scale was given only in the first session. The "review of previous week" included review of items on the PES accomplished in the previous week.



**Table 2.**

Mental Health Therapist (MHT) *delivery* of treatment components to nursing home staff as reported by the MHTs in their treatment logs.

Item	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Average All Weeks
<b>Staff Meeting Occurred</b>	<b>90.6%</b>	<b>80.6%</b>	<b>81.3%</b>	<b>87.1%</b>	<b>65.5%</b>	<b>70.4%</b>	<b>53.6%</b>	<b>79.3%</b>	<b>61.5%</b>	<b>65.5%</b>	
<b>Reinforced Staff for Effort</b>	<b>90.3%</b>	<b>83.9%</b>	<b>90.3%</b>	<b>84.4%</b>	<b>76.9%</b>	<b>72.0%</b>	<b>73.7%</b>	<b>96.2%</b>	<b>95.7%</b>	<b>96.0%</b>	
<b>Discussed Barriers</b>	<b>86.7%</b>	<b>89.3%</b>	<b>81.5%</b>	<b>80.6%</b>	<b>83.3%</b>	<b>87.5%</b>	<b>88.9%</b>	<b>80.0%</b>	<b>61.9%</b>	<b>78.3%</b>	
<b>Gave info about Depression</b>	<b>62.1%</b>	<b>75.0%</b>	<b>70.4%</b>	<b>70.0%</b>	<b>73.9%</b>	<b>79.2%</b>	<b>88.9%</b>	<b>40.0%</b>	<b>25.0%</b>	<b>41.7%</b>	
Review of Session Agenda	34.6%	37.9%	32.1%	37.9%	25.0%	32.0%	41.2%	74.1%	69.6%	60.0%	
Gave Info About Dementia *	32.1%	32.1%	39.3%	36.7%	43.5%	37.5%	44.4%	26.1%	16.7%	25.0%	
Discussed Behavior Mgmt. *	34.8%	26.1%	27.3%	30.8%	38.9%	27.3%	57.1%	44.0%	42.9%	30.4%	
Discussed Family Issues *	21.4%	32.1%	33.3%	23.3%	21.7%	37.5%	38.9%	47.1%	33.3%	62.5%	
Discussed Resources	40.7%	60.0%	47.6%	56.5%	25.0%	29.4%	44.4%	52.4%	52.9%	57.1%	
Discussed Maintenance /Care Plan	34.6%	37.9%	32.1%	37.9%	25.0%	32.0%	41.2%	74.1%	69.6%	60.0%	
Mean (SD) Staff Minutes with Resident	N/A	174.00 (141.68)	172.14 (162.88)	142.88 (148.23)	197.58 (193.41)	234.18 (191.92)	209.52 (182.14)	192.42 (168.90)	180.00 (181.72)	218.28 (212.11)	

Note: Bolded items identify staff-related core components (see Figure 1).

\* These elements were not discussed when not relevant, i.e., when no diagnosis of dementia existed, absence of behavior problems, no family involvement.

Means and standard deviation of receipt and enactment variables compared across outcome groups for post-treatment, and 3- and 6-month follow-up assessments.

**Table 3.**

Post-Treatment Outcomes					
Variable	Worse N=1	No Change N=17	Improved N=4	Remitted N=19	Total N=41
Mean # Planned Activities per Week*	5.3 (0)	4.23 (1.56)	4.35 (0.89)	5.79 (1.57)	4.99 (1.66)
Mean # Completed Activities Per Week**	4.44 (0)	2.84 (1.67)	3.04 (1.37)	4.77 (1.32)	3.79 (1.70)
Mean Time with Activities Staff (in Minutes/Week)	83.33 (0)	110.86 (72.52)	144.72 (83.03)	289.63 (188.02)	195.92 (161.67)
Number of Sessions	9 (0)	6.29 (3.58)	9.00 (2.00)	7.79 (3.38)	7.14 (3.53)
Three-Month Outcomes					
Variable	Worse N=7	No Change N=8	Improved N=7	Remitted N=19	Total N=41
Mean # Planned Activities per Week*	4.57 (1.33)	4.20 (1.36)	4.21 (1.46)	5.76 (1.69)	4.99 (1.66)
Mean # Completed Activities Per Week**	4.56 (0.95)	2.62 (1.08)	2.57 (1.43)	4.59 (1.61)	3.79 (1.70)
Mean Time with Activities Staff	259.44 (262.88)	103.4 (67.24)	173.03 (118.68)	211.84 (143.96)	195.92 (161.67)
Number of Sessions**	4.57 (4.67)	5.38 (3.50)	8.43 (1.72)	8.74 (2.42)	7.14 (3.53)
Six-Month Outcomes					
Variable	Worse N=15	No Change N=7	Improved N=5	Remitted N=14	Total N=41
Mean # Planned Activities per Week	4.60 (1.55)	4.25 (1.47)	4.95 (0.87)	5.79 (1.86)	4.99 (1.66)
Mean # Completed Activities Per Week <sup>+</sup>	3.74 (1.96)	2.48 (1.10)	3.51 (1.00)	4.54 (1.63)	3.79 (1.70)
Mean Time with Activities Staff	186.83 (143.31)	102.58 (75.15)	170.00 (154.27)	250.28 (198.64)	195.92 (161.67)
Number of Sessions <sup>+</sup>	6.67 (3.72)	5.00 (3.61)	9.60 (0.55)	8.36 (2.79)	7.14 (3.53)

\* p < .05

strong outcome comparing  $p < .10$

$p < .10$   
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Pairwise comparisons of improved vs. not improved at post-treatment, three-, and six-month follow-ups, for receipt and enactment variables.

**Table 4.**

Variable	Post-Treatment			Three Month Follow-up			Six Month Follow-up		
	<i>t</i>	<i>DF</i>	<i>p</i>	<i>t</i>	<i>DF</i>	<i>p</i>	<i>t</i>	<i>DF</i>	<i>p</i>
# Planned Activities	-2.72	39	.010	-3.58	39	.001	-2.00	39	.052
# Completed Activities	-3.02	33	.005	-3.31	33	.002	-1.73	33	.093
Mean Staff Time	-2.82	35	.008	-.297	35	.768	-1.70	35	.098
Number of Sessions	.23	39	.816	-2.17	39	.036	-1.29	39	.21