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Falls as adverse events in psychosocial treatment of depression: Findings from a clinical trial in nursing homes

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ABSTRACT

Falls pose a significant health risk for nursing home residents and are associated with depression and medical treatments for depression. Data on falls as an adverse event to psychosocial treatments are lacking. We examined risk of falls as an adverse event in a clinical trial of a behavioral treatment for depression. Participants were 82 depressed nursing home residents. Adverse events were recorded at each research contact. We used the rate ratio based on the respective incidence densities in the treatment and control groups to measure association between fall rate and treatment. The treatment group had almost six times higher risk of falls than the control group, a statistically significant association. Findings suggest that it may be of value to include statistical analysis of falls as adverse events in trials of behavioral interventions for depression.

Falls are a serious health event for older adults, and affect approximately two thirds of nursing home residents [10]. Depression is common in nursing homes and is associated with risk of falls [5]. Medical treatments for depression are also associated with increased risk of falls [4,13]. Adverse events are not frequently analyzed in clinical trials for behavioral interventions, and little is known about falls as an adverse event secondary to psychosocial treatments for depression. As a part of our data safety and management plan in a clinical trial of a behavioral intervention for depression [9], we tracked and analyzed adverse events. The purpose of the present study was to assess the risk of falls associated with a psychosocial depression treatment.

1. Method

We analyzed data from a cluster-randomized controlled trial of a 10-week psychosocial treatment for depression designed to increase activation through increasing pleasant events (See Refs. [8,9] for primary outcomes and clinical trial details). Briefly, 23 nursing facilities from Kentucky and Indiana were randomly assigned to either the experimental or treatment-as-usual (TAU) conditions. There were 336 residents in the participating nursing homes who were eligible by screening; 157 refused participation and 150 residents provided informed consent. Of those, 82 were eligible after a more extensive assessment to determine depression diagnosis (inclusion criterion) and exclude those with Mini-Mental State Examination scores below 14 (those unable to complete study measures); 42 were randomized to the experimental group, and 40 to the control group. Participants were assessed at baseline, post-treatment, and at 3- and 6-month follow-ups.

1.1. Measures

During a two-week baseline assessment and the 10-week intervention phase, research staff met with participants for at least one visit per week. Visits with treatment recipients were for 30–60 min intervention sessions. Visits with TAU participants were for 5–30 min, to collect data on current mood and physical events occurring during the previous week. For all participants there were two brief visits during the two-week follow-up periods at 3 months and at 6 months. Each time a research staff member was in contact with a participant they completed a checklist of possible adverse events, which included the following: participant complaint of fatigue related to the intervention, confidentiality breach, increased depression severity, suicidal ideation, severe medical set-back (e.g., hospitalization, pneumonia), resident died, falls, or "other." When research staff became aware of adverse events from nursing home staff or other sources, they also completed this checklist. Research

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staff rated each adverse event as mild, moderate, or severe, and as related or unrelated to the study activities. Adverse event ratings were also reviewed quarterly by an independent data safety monitor.

At baseline and follow-up assessments, we extracted the following from the medical record: demographic information, physical functioning, number of medications, and medical diagnoses. Research staff also reviewed medication records for use of antidepressant and other psychotropic medications.

1.2. Participants

Participants had a mean age of 75.16 ($SD = 12.11$), a mean of 11.56 years of education ($SD = 3.35$), and had been in the facility an average of 37.70 months ($SD = 74.56$). The sample was 34.6% men and 92.6% white of European origin. All had a depressive diagnosis determined at baseline via a structured clinical interview conducted by a research psychologist. The participants had an average of 9.31($SD = 4.20$) non-mental health medical diagnoses and over 81% were receiving antidepressant medications. Baseline comparisons of the experimental and TAU groups on demographics and health variables showed that the groups were similar with the exception that the experimental group had fewer days on an antidepressant at baseline ($t = 2.18$, $DF = 54$, $p = 0.034$), more education ($t = 2.46$, $DF = 60$, $p = 0.017$), and a larger number of physician visits in the three months prior to baseline assessment ($t = 2.56$, $DF = 6.6$, $p = 0.022$) than the TAU group. The mean duration of antidepressant usage for the primary antidepressant was approximately 9 months.

1.3. Data analyses

Because the amount of follow-up varied greatly among study participants, we used the rate ratio based on the respective incidence densities in the two groups as the measure of association so that the number of person-days could be taken into account. Separately for each adverse event, exact inferential methods for the ratio of two Poisson parameters were used to find a 95% confidence interval for the true rate ratio, and to test the null hypothesis that the true rate ratio was equal to one. The mid-P adjustment was used to reduce the conservatism of the exact methods [1]. Hypothesis tests were two-tailed, and were performed using a significance level of 0.05. All statistical analyses were performed using [12]; Cytel Software Corp., Cambridge, MA).

2. Results

Table 1 shows the adverse events data recorded during the project; no adverse event other than falls was significantly different between the two groups. (The difference between groups on "increased depression severity" approached significance; as might be expected given the results of the clinical trial [9] the control group had more recorded instances of this adverse event). There were 13 falls reported over 20,739 person-days of follow-up, or an average of 252.91 days per participant (range: 9–336 days). Seven participants fell once, and three participants fell twice. Most participants did not fall, but 11 falls were experienced by members of the treatment group, as compared to only 2 falls in the TAU group (2 individuals, one fall each). The fall rate in the treatment group was nearly 6 times that of the control group, an association that was statistically significant.

Participant time in the study ranged from 10 to 101 days at the time of their first fall. The mean elapsed time in the study for all falls was 73.31 days (SD = 43.68); most of the treatment group falls occurred during the last 3 weeks of treatment or the 3 months following. Two of the falls were coded as directly related to treatment activities.

3. Conclusion

Our findings support the hypothesis that a psychosocial treatment for depression can increase the risk of falls in nursing home patients, and highlight the importance of measuring and analyzing adverse events in behavioral trials. The participants in this randomized, controlled trial who received the active intervention were almost six times more likely to fall than those in the treatment as usual condition. This study involved secondary analysis of a clinical trial, and limitation on power prevented us from performing additional statistical analyses to examine concurrent risk factors. Further, ascertainment of falls is not straightforward (e.g., [7]), and our method of recording adverse events could have resulted in falls being missed. Minor falls that did not result in patient injury or distress may not have been reported to the research staff. Also, there was no weekly monitoring between follow-up periods, so falls that occurred during those periods, unless severe, may have been missed. These limitations may have led to underestimating falls, especially minor, non-injury falls. Because most falls that we recorded occurred during the 12 weeks when all participants were assessed weekly, our data only support the hypothesis that the risk of falling is increased during the active treatment period. Having better data about falls during the follow-up period could help

Table 1
All adverse events by treatment group.

Adverse event	Group	# of events/days of person-time	Rate	Rate ratio (95% C.I.)	P-value
Fall	Treatment	11/10,052	0.001094	5.85 (1.45–38.84)	0.010
	Control	2/10,687	0.000187		
Resident complained of fatigue related to intervention	Treatment	1/11,256	0.000089	0.99 (0.03–38.51)	0.994
	Control	1/11,115	0.000090		
Increased depression severity	Treatment	1/11,510	0.000087	0.15 (0.01–1.02)	0.053
	Control	6/10,414	0.000576		
Suicidal ideation	Treatment	3/11,089	0.000271	1.44 (0.21–12.08)	0.722
	Control	2/10,622	0.000188		
Severe medical set-back	Treatment	5/10,818	0.000462	0.55 (0.17–1.64)	0.293
	Control	9/10,707	0.000841		
Resident died	Treatment	7/11,371	0.000616	0.99 (0.33–2.95)	0.985
	Control	7/11,255	0.000622		
Other	Treatment	8/10,317	0.000775	0.56 (0.22–1.35)	0.199
	Control	13/9366	0.001388		

determine whether treated individuals continued to have more falls post-treatment. This is an important question clinically, as it speaks to the need for ongoing monitoring of risk of falls after treatment termination.

The participants in the current study shared risk factors for falls, including depression, multiple chronic illnesses, functional impairment, and antidepressant medication. Even with all of these risk factors in common, those treated with an effective psychosocial treatment for depression had a significantly higher rate of falls than those who were not. If replicated, these findings have both clinical and research implications. In terms of clinical practice, it may be important for mental health practitioners to consider risk of falls during any treatment for depression, to assess regularly for safety, and to consider whether treatment for depression should be augmented by fall prevention practices. In terms of research, falls should be tracked as a potential adverse event in psychosocial treatment studies of depression, especially during treatment and follow-up periods. More generally, this research suggests that there could be value in monitoring and analyzing adverse events for behavioral interventions, a practice that is rarely reported.

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Disclosures

The authors have no conflicts of interest.

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