



## DEPARTMENT OF VETERANS AFFAIRS (VA)

### A Pilot Randomized Controlled Trial of a Depression and Disease Management Program Delivered by Telephone

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#### Introduction

Depression is the most common mental disorder treated in primary care. It occurs in 15 to 20% of patients with chronic illness, a prevalence almost twice that found in the general population.<sup>1-3</sup> As well, people with chronic illness compounded by depression experience greater degrees of morbidity and mortality than do their non-depressed counterparts.<sup>1, 4-9</sup>

Though depression is treatable with pharmacologic and psychotherapeutic interventions, two major obstacles can stand in the way of optimal treatment of depression in those suffering chronic illness: 1) co-morbid medical illness is associated with poorer response to antidepressants<sup>10,11</sup>, and 2) access to care can be problematic, particularly for psychotherapy, which typically requires weekly visits.

Of those under treatment for depression, two-thirds prefer psychotherapy over medications, with psychotherapy having been proven as effective as medications in managing mild to moderate depression. However, only 20–40% of those referred for psychotherapy eventually receive it due to barriers such as cost, stigma and travel, the latter particularly challenging for those living in rural areas.

Telephone-administered psychotherapy provides a possible means to bypass some of the barriers faced by rural patients. This study describes an innovative

#### Key Findings

A comparison of three treatment interventions—**Usual Care**, **telephone-delivered Illness Management**, and **telephone-delivered Illness Management combined with Psychotherapy**—among 83 medically ill rural Veterans with depression demonstrated that

- Forty-five percent of those undergoing telehealth-delivered Illness Management with Psychotherapy experienced an improvement in depression symptoms, while 32% showed improvement in the Illness Management group, and 26% in the Usual Care group, as measured by PHQ-9. The results of another measure (BDI-II) showed lesser positive effects.
- Self-care and health-related quality of life showed no differences between groups.

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telehealth intervention designed to improve the effectiveness of two earlier studies on tele-administered depression treatment.<sup>12–13</sup> It addresses specifically the barriers to effective care faced by medically-ill Veterans. One prior randomized controlled trial of phone-based therapy for Veterans in primary care did not demonstrate effectiveness in reducing depressive symptoms.<sup>13</sup>

**First**, the intervention combined psychotherapy with a chronic disease management program<sup>14</sup> based on the theory that any depression treatment that does not address the co-morbid chronic illness will have limited success. The intervention included daily interactive home tele-monitoring of chronic illness symptoms.

**Second**, the study addressed three common primary care illnesses often associated with depression: diabetes, hypertension, and chronic pain.<sup>15–17</sup> Evidence had indicated that each of these illnesses appears to bear a bidirectional relationship with depression in which one condition exacerbates another.<sup>4–6, 18–20</sup>

**Third**, the intervention was conducted entirely by telephone to reduce travel burden to Veteran patients and to facilitate treatment dissemination.

## Methods

### Subjects

The study area included rural VA medical centers in North Dakota and Iowa where many Veterans have to travel more than 8 hours to receive in-person care. Eligible subjects were those with uncontrolled hypertension, uncontrolled diabetes, or non-cancerous chronic pain. Patients were excluded if they lived in a long-term care facility, had a projected life expectancy of less than three months, had an active malignancy, marked vision or hearing impairment, a significant psychiatric illness or if they were currently receiving psychotherapy. Eligible patients scoring 5 or higher on the 9-item Patient Health Questionnaire (PQH-9)<sup>21</sup> were included in the subject pool.

### Study Intervention Arms

- **Usual Care:** Patients continued to receive their usual medical and/or psychiatric care from their providers without any type of telephone intervention.

- **Illness Management Only:** Via telephone, patients discussed medication adherence, diet, wellness behaviors, and symptom monitoring with wellness coaches. Patients also called a toll-free number every day and reported on illness factors such as blood pressure, blood glucose, and/or daily pain rating, each area subject to discussion with a study coach.
- **Combined Illness Management and Psychotherapy:** This group received all the aspects of the IMO group, plus depression intervention combining aspects of Interpersonal Psychotherapy and Behavioral Activation to help patients cope with the emotional effects of suffering a chronic illness.

All patients completed self-administered assessments of the primary and secondary outcomes at baseline, week 5, and week 10 (post-intervention). Assessment areas included 1) *depression severity*, 2) *health-related quality of life*, and 3) *engagement in illness management behaviors*. The Beck Depression Inventory-II<sup>22</sup> as well as the PQH-9 were administered as a measure of depression. Health-related quality-of-life was assessed using selected subscales for the RAND 36.<sup>23</sup> Engagement in illness management behaviors was assessed using the RAND Medical Outcomes Study Medical Adherence Questionnaire.<sup>24</sup>

### Statistical analysis

Linear mixed-effect regression models were used to compare the change in the treatment arms over the three time points. Specific contrast statements compared the Combined with the Usual Care group and Combined with the Illness Management Only group to test for time\*treatment group interactions expressed by change between groups over time.

## Findings

### Sample

The mean age of the total 83 subjects was 64.5 (SD=9.1), ranging between 41 and 88 years. The sample was predominantly white and male (94.1% and 94.1%, respectively). About 2/3 of the sample had at least some college education (67%), while 10% had completed high school or received a GED and 9% had not achieved a high school level of education. The distribution of chronic illness was comparable between groups.

Total sample size for analyses:

- Usual Care group: n=23
- Illness Management Only group: n=31
- Combined Care group: n=29

### Depression outcomes

Table 1 shows the means and standard errors of PQH-9 and BDI-II scores for each of the three treatment arms. Response on the PHQ-9 was defined as a drop of 5 or more points, while response on the BDI-II was defined as a drop of 50% or more. A planned contrast between the Combined intervention and Usual Care groups revealed a significant group\*time interaction for the total PHQ score and the total BDI-II score. The planned contrast between the Combined group and Illness Management Only was not significant for either the PHQ-9 total score or the BDI-II total score.

### Medical outcomes

Total score on the RAND Medical Outcomes Study adherence measure *increased only slightly* in each group with no significant difference between groups. Likewise, groups did not differ in regard to the RAND-36 physical function measures.

### Conclusions

In this preliminary study, a combined illness management and psychotherapy intervention conducted entirely by telephone yielded a significant decline in depressive symptoms when compared with usual care. However, there was no significant difference in decline in depressive symptoms between the Combined intervention group and Illness Management Only group. As well, none of the groups showed meaningful change in chronic disease self-management or health-related quality of life over the ten-week study period.

**Table 1. Group Means, Standard Errors, and Planned Comparisons for Depression Outcomes**

	Combined (n=29)		Illness Management Only (n=31)		Usual Care (n=23)		P Value
	Baseline	Week 10	Baseline	Week 10	Baseline	Week 10	
PHQ-9							
Mean (se)	12.5 (1.0)	8.2 (1.0)	13.2 (1.0)	10.4 (1.0)	11.2 (1.1)	10.4 (1.1)	
Response (drop 5 points or more)	---	13 (45%)	---	10 (32%)	---	6 (26%)	0.38
BDI-II							
Mean (se)	19.1 (2.0)	15.3 (1.8)	23.9 (1.9)	20.5 (1.8)	20.2 (2.2)	21.0 (2.0)	
Response (50% drop or more)	---	7 (24%)	---	2(6%)	---	2 (9%)	0.13

Mixed Effects Regression Models Outcome = Total Score PHQ-9:

Planned Comparison Combined vs. Usual Care, group x time,  $t = -2.5$ ,  $p > t = 0.01$ . Cohen's  $d = 0.74$

Planned Comparison Combined vs. Illness Management Only, group x time,  $t = -0.9$ ,  $p > t = 0.39$ . Cohen's  $d = 0.32$

Mixed Effects Regression Models Outcome = Total Score BDI-II:

Planned Comparison Combined vs. Usual Care, group x time,  $t = -2.2$ ,  $p > t = 0.03$ . Cohen's  $d = 0.63$

Planned Comparison Combined vs. Illness Management Only, group x time,  $t = 0.18$ ,  $p > t = 0.9$ . Cohen's  $d = 0.04$



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## Impact

- A holistic approach using telephone-delivered intervention is an effective means of treating medical illness accompanied by depression in rural Veterans whose treatment would otherwise be hampered by cost, social stigma, and travel barriers.
- This study adds to the evidence base for the effectiveness of mental health treatment delivered by communication devices. Future larger randomized clinical trials to characterize the medical outcomes in adopting such a promising approach are needed.

## References

1. Katon, W., E.H. Lin, and K. Kroenke, *The association of depression and anxiety with medical symptom burden in patients with chronic medical illness*. Gen Hosp Psychiatry, 2007. **29**(2): p. 147-55.
2. Kroenke, K., *Patients presenting with somatic complaints: epidemiology, psychiatric comorbidity and management*. Int J Methods Psychiatr Res, 2003. **12**(1): p. 34-43.
3. Wells, K.B., J.M. Golding, and M.A. Burnam, *Psychiatric disorder in a sample of the general population with and without chronic medical conditions*. Am J Psychiatry, 1988. **145**(8): p. 976-81.
4. Georgiades, A., et al., *Changes in depressive symptoms and glycemic control in diabetes mellitus*. Psychosom Med, 2007. **69**(3): p. 235-41.
5. Golden, S.H., *A review of the evidence for a neuroendocrine link between stress, depression and diabetes mellitus*. Curr Diabetes Rev, 2007. **3**(4): p. 252-9.
6. Gonder-Frederick, L.A., et al., *Mood changes associated with blood glucose fluctuations in insulin-dependent diabetes mellitus*. Health Psychol, 1989. **8**(1): p. 45-59.
7. Jonas, B.S., P. Franks, and D.D. Ingram, *Are symptoms of anxiety and depression risk factors for hypertension? Longitudinal evidence from the National Health and Nutrition Examination Survey I Epidemiologic Follow-up Study*. Arch Fam Med, 1997. **6**(1): p. 43-9.
8. Jonas, B.S. and J.F. Lando, *Negative affect as a prospective risk factor for hypertension*. Psychosom Med, 2000. **62**(2): p. 188-96.
9. Spitzer, R.L., et al., *Health-related quality of life in primary care patients with mental disorders. Results from the PRIME-MD 1000 Study*. JAMA, 1995. **274**(19): p. 1511-7.
10. Iosifescu, D.V., *Treating depression in the medically ill*. Psychiatr Clin North Am, 2007. **30**(1): p. 77-90.
11. Iosifescu, D.V., B. Bankier, and M. Fava, *Impact of medical comorbid disease on antidepressant treatment of major depressive disorder*. Curr Psychiatry Rep, 2004. **6**(3): p. 193-201.
12. Mohr, D.C., et al., *The Effect of Telephone-Administered Psychotherapy on Symptoms of Depression and Attrition: A Meta-Analysis*. Clin Psychol (New York), 2008. **15**(3): p. 243-253.
13. Mohr, D.C., et al., *Telephone-administered cognitive behavioral therapy for veterans served by community-based outpatient clinics*. J Consult Clin Psychol, 2011. **79**(2): p. 261-5.
14. Lorig, K., et al., *Living a health life with chronic conditions. 2nd edition: Self-management of heart disease, arthritis, stroke, diabetes, asthma, bronchitis, emphysema & others*. 2nd ed. 2000, Boulder, CO: Bull Publishing Company.
15. Anderson, R.J., et al., *The prevalence of comorbid depression in adults with diabetes: a metaanalysis*. Diabetes Care, 2001. **24**(6): p. 1069-78.
16. Bair, M.J., et al., *Depression and pain comorbidity: a literature review*. Arch Intern Med, 2003. **163**(20): p. 2433-45.
17. Wolff, J.L., B. Starfield, and G. Anderson, *Prevalence, expenditures, and complications of multiple chronic conditions in the elderly*. Arch Intern Med, 2002. **162**(20): p. 2269-76.
18. Goodnick, P.J., et al., *Sertraline in coexisting major depression and diabetes mellitus*. Psychopharmacol Bull, 1997. **33**(2): p. 261-4.
19. Gulseren, L., et al., *Comparison of fluoxetine and paroxetine in type II diabetes mellitus patients*. Arch Med Res, 2005. **36**(2): p. 159-65.
20. Rabkin, J.G., E. Charles, and F. Kass, *Hypertension and DSM-III depression in psychiatric outpatients*. Am J Psychiatry, 1983. **140**(8): p. 1072-4.
21. Spitzer, R.L., K. Kroenke, and J.B. Williams, *Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders. Patient Health Questionnaire*. JAMA, 1999. **282**(18): p. 1737-44.
22. Beck, A., R.A. Steer, and M. Garbin, *Psychometric properties of the Beck Depression Inventory: Twenty-five years of evaluation*. Clinical Psychology Review, 1988. **8**: p. 77-100.
23. Ware Jr., J., et al., *SF-36 Health Survey: Manual and interpretation guide*. 1993, Boston: The Health Institute, New England Medical Center.
24. Hays, R.D., et al., *The impact of patient adherence on health outcomes for patients with chronic disease in the Medical Outcomes Study*. J Behav Med, 1994. **17**(4): p. 347-60.