A Telephone-Based Program to Provide Symptom Monitoring Alone vs Symptom Monitoring Plus Care Management for Late-Life Depression and Anxiety: A Randomized Clinical Trial

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**IMPORTANCE** Mental health (MH) conditions are undertreated in late life. It is important to identify treatment strategies that address variability in treatment content and delivery and take individual-specific symptoms into account, particularly among low-income, community-dwelling older adults.

**OBJECTIVE** To evaluate program feasibility and MH outcomes among community-dwelling older adults randomized to 1 of 2 treatment arms of varying intensity of evidence-based, collaborative MH care management services (ie, the Supporting Seniors Receiving Treatment and Intervention [SUSTAIN] program) that provide standardized, measurement-based, software-aided MH assessment and symptom monitoring and connection to community resources via telephone.

**DESIGN, SETTING, AND PARTICIPANTS** Trial participants were 1018 older, community-dwelling, low-income adults prescribed an antidepressant or anxiolytic by a primary care or non-MH professional and experiencing clinically significant MH symptoms at intake. The participant subsample was drawn from a larger parent sample of older adults enrolled in the SUSTAIN program. Individuals were randomized to receive MH symptom monitoring alone (hereafter monitoring alone) or MH symptom monitoring plus care management (hereafter care management) provided by an MH professional. Baseline characteristics were examined, and changes in clinical MH outcomes were evaluated at 3-month and 6-month follow-up. The study dates were August 5, 2010, to May 5, 2014.

**INTERVENTIONS** Monitoring alone or care management delivered by an MH professional.

**MAIN OUTCOMES AND MEASURES** Overall MH functioning (primary) and depressive and anxiety symptoms.

**RESULTS** A total of 509 participants were randomized to the monitoring alone group and 509 to the care management group; 377 and 401 completed ≥2 research assessments in the monitoring alone and case management groups, respectively. Compared with those randomized to monitoring alone, individuals randomized to care management showed greater improvements in the 3 domains of MH functioning (β [SE], 0.36 [0.12]; 95% CI, 0.12 to 0.60; P = .004), depressive symptoms (β [SE], −0.20 [0.06]; 95% CI, −0.32 to −0.09; P < .001), and anxiety symptoms (β [SE], −0.23 [0.05]; 95% CI, −0.33 to −0.14; P < .001) over time.

**CONCLUSIONS AND RELEVANCE** The SUSTAIN program, which provides assessment, monitoring, care management, and brief therapies for MH symptoms and needs in primary care settings, is feasible and scalable. A more intense level of care (ie, symptom monitoring plus care management) is associated with more favorable individual outcomes for low-income, community-dwelling older adults experiencing clinically significant MH symptoms.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT02440594


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Mental health (MH) conditions affect individuals across the life course but are particularly underidentified, undertreated, and detrimental in later life. Such conditions serve as the catalyst for a variety of negative outcomes in older adulthood, including cognitive decline, physical disability and morbidity, loss of independence, institutionalization, and ultimately mortality. One in 5 older adults experiences some form of MH condition, but less than 10% report receiving any MH treatment. Among those who seek or receive treatment, most do so when in primary care. To address logistic and system-level barriers and optimize outcomes among individuals receiving MH treatment in primary care, several teams have developed and evaluated a collaborative MH care model. This model includes MH care managers who provide education, counseling, and decision support to patients and their primary care providers; a licensed MH professional (eg, psychiatrist) who supervises the care managers; and the use of an algorithm to guide and adjust pharmacological and nonpharmacological treatment plans. A key feature of collaborative MH care is the use of measurement-based care, which involves frequent monitoring, as well as standardized assessments, tracking tools, and treatments that are individualized and adapted based on patient preferences, symptoms, medication adherence and tolerability, and treatment response. This greater precision in patient monitoring enables accurate and quick patient and health care professional feedback as well as modification of treatment when needed.

The evidence base for measurement-based, collaborative MH care models is strong. However, although measurement-based MH care management (CM) programs offer decision support and reduce the treatment heterogeneity that often characterizes MH care, questions remain regarding the relative effectiveness of different treatment strategies for various populations. For example, several collaborative care trials have shown limited benefits of both psychotropic medication and intensive MH CM for older adults with subsyndromal or even mild depressive disorder. In addition, almost all of the randomized clinical trials to date have focused on multifaceted programs delivering intense services. There is little evidence regarding the level of patient or health care professional support that is needed to achieve positive outcomes. Understanding the conditions in which varying intensities of MH monitoring and CM are most effective is important at many levels (eg, choosing the most appropriate treatments to attain individual-level improvement, achieving cost-efficient care, and formulating medical reimbursement policies).

Moreover, although collaborative care models have been successfully implemented in a variety of settings, there is much value to be gained from examining care among specific subgroups of older adults who may be particularly vulnerable to negative outcomes. For example, older, community-dwelling adults with low income not only are more susceptible to MH conditions, such as depression, but also respond less favorably to psychotherapy and pharmacotherapy than their more affluent counterparts. Factors such as medical and psychiatric comorbidity and a lack of access to and knowledge of MH resources further complicate MH treatment for this group. Therefore, collaborative care models that can help identify and more comprehensively meet the MH and psychosocial needs of this vulnerable group are needed.

This randomized clinical trial sought to evaluate the feasibility and relative effectiveness of 2 different levels of integrated MH care (ie, symptom monitoring alone [MA] vs symptom monitoring plus CM) offered as part of an evidence-based, collaborative MH CM clinical service (ie, the Supporting Seniors Receiving Treatment and Intervention [SUSTAIN] program) for older adults. The SUSTAIN program provides clinical MH CM services to low-income older adults enrolled in the state of Pennsylvania’s Pharmaceutical Assistance Contract for the Elderly (PACE)/Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier (PACENET) pharmacological assistance program who are newly prescribed a psychotropic medication, as well as to their primary care providers. Program features include (1) case finding and enrollment of older adults from a diverse community sample; (2) standardized, measurement-based, software-aided MH assessment and symptom monitoring that can be delivered by telephone and is thus available to primary care practices regardless of location, size, or resources; and (3) CM, which includes both connection to local community agencies and services and brief therapies for a wide variety of behavior symptoms and disorders (eg, depression, anxiety, and at-risk drinking). We hypothesized that, compared with individuals randomized to receive MH symptom MA (hereafter the MA arm), those randomized to receive MH symptom monitoring plus CM (hereafter the CM arm) would demonstrate more favorable clinical outcomes, including better overall MH functioning (primary outcome) and fewer depressive and anxiety symptoms.

Methods

Study Sample

Data were extracted for 1018 PACE/PACENET beneficiaries who were enrolled in the SUSTAIN program from August 5, 2010, to May 5, 2014, and randomized to receive either MA or CM (Figure 1). Data analyses were conducted from January 30, 2015, to August 31, 2015. Data analyses were conducted from January 30, 2015, to August 31, 2015. To obtain a representative sample, the PACE/PACENET program used a stratified sampling method for the identification and referral of eligible beneficiaries to the SUSTAIN program. Beneficiaries were stratified based on county (urban vs rural) and medication type (antidepressant vs anxiolytic), with individuals randomly selected from each stratum. Individuals living in rural areas were oversampled. To be eligible for enrollment in the SUSTAIN program and inclusion in the present analyses, individuals must have met the following criteria: (1) age 65 years or older, (2) residence in a noninstitutionalized setting, (3) evidence of at least 1 new prescription filled (written by a nonpsychiatric health care professional) for an antidepressant or anxiolytic, and (4) presence of clinically significant symptoms, defined as having a Patient Health Questionnaire 9-Item (PHQ-9) score of 5 to 24 or...
a Generalized Anxiety Disorder 7-Item Scale (GAD-7) score of at least 5 or meeting criteria for panic disorder. Individuals were excluded if they demonstrated severe cognitive impairment or reported very mild or severe (ie, warranting referral to specialty care) baseline symptoms. Finally, while most health care professionals were in a primary care practice (90.0% [916 of 1018]), individuals were identified from several other nonpsychiatric settings, including cardiology (2.1% [21 of 1018]), neurology (1.4% [14 of 1018]), and rheumatology (1.0% [10 of 1018]).

Study Procedures
An overview of the procedures and components of the overall SUSTAIN program (formerly named the PACE/PACENET Behavioral Health Laboratory program) has been published elsewhere. The full trial protocol and an outline of the clinical procedures are provided in Supplement 1. Clinical staff received extensive training, and fidelity to the intervention was ensured via weekly supervision with the medical director (J.E.S.) based on the Foundations for Integrated Care program. All study procedures were approved by the University of Pennsylvania’s Institutional Review Board. Individuals provided oral informed consent at the time of the baseline assessment, and every other individual was randomized to the CM arm. Oral informed consent was obtained for the assessments at 3 and 6 months after randomization, which mirrored the baseline interview in content. Research personnel were not masked to intervention arm randomization.

MA Arm
Individuals randomized to the MA arm completed a baseline assessment and up to 4 brief follow-up assessments during which time medication adherence, adverse effects, and symptoms were monitored. Interviews were conducted by health technicians or behavioral health providers (BHPs) and were completed by direct entry of clinical data into a software program (BHL, version 5.3; Capital Solution Design). In addition to sociodemographics and a general needs assessment, specific, standardized, validated scales administered at baseline included the following: the Blessed Orientation-Memory-Concentration Test, the Mini-International Neuropsychiatric Interview (includes psychosis, mania, panic disorder, and alcohol abuse/dependence modules), the PHQ-9 (a brief depression symptom severity measure), the 5-item Paykel Scale for suicide ideation, the 12-Item Short-Form Health Survey (for overall physical [PCS] and mental component subscale [MCS] functioning), and the GAD-7 for generalized anxiety symptom severity. On completion of the baseline assessment, a summary of the individual’s outcomes was generated for his or her prescribing professional. Individuals also were mailed educational materials regarding specific reported symptoms.

Individuals in the MA arm also received up to 4 brief (5-10 minutes) structured assessments after the baseline assessment. These brief follow-up contacts took place during the initial 12 weeks of pharmacological treatment and were designed to monitor adherence, adverse effects, and response to treatment. Structured assessments included the PHQ-9, the GAD-7, and questions regarding irritability and sleep. A progress report was provided to the prescribing professional after each interview to help in treatment planning and alert him or her to special issues (especially safety concerns).

CM Arm
Individuals randomized to the CM arm received all monitoring services described above plus CM delivered by BHPs who had expertise in MH assessment and were well versed in delivery of algorithm-based management strategies for disorders such as depression and anxiety. To help supplement and support the prescribed treatment, the roles of BHPs included facilitating treatment, engaging individuals in the treatment process, encouraging acceptance and adherence to treatment recommendations, and monitoring safety, tolerability, and response to treatment, and providing educational and problem-focused therapy using motivational interviewing techniques in a manner consistent with guidelines by the

Figure 1. CONSORT Diagram of Participant Randomization

CM indicates care management; CONSORT, Consolidated Standards of Reporting Trials; MA, monitoring alone; MH, mental health; PACE/PACENET, Pharmaceutical Assistance Contract for the Elderly/Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier; and SUSTAIN, Supporting Seniors Receiving Treatment and Intervention.
Agency for Healthcare Research and Quality. Where appropriate, BHPs also connected individuals with local community services and resources. The frequency and number of contacts for each participant varied, but individuals received on average 5 telephone calls over the span of approximately 12 weeks. Individuals in the CM arm also received maintenance telephone calls at 4-month, 5-month, and 6-month follow-up. Written updates and algorithm-based recommendations were provided to the prescribing professional at each assessment or as clinically indicated.

Outcome Assessments
Overall MH functioning (ie, the 12-Item Short-Form Health Survey MCS score) was the primary outcome. Secondary outcomes included the PHQ-9 and GAD-7 symptom severity scores.

Statistical Analysis
Initial descriptive, univariable analyses included means and standard deviations for continuous variables and frequencies and percentages for binary variables. Baseline comparisons between treatment arms were made using the t test for continuous variables and the χ² test for categorical variables. There was sufficient power (89%) for a 2-sided test (α = .05) to detect a small effect size of 0.20 for the primary outcome.

To test our primary hypotheses, differences between the MA and CM arms were estimated using intent-to-treat, mixed-effects linear regression models of longitudinal data extracted from the baseline and 3-month and 6-month follow-up interviews. Individual outcomes included the 12-Item Short-Form Health Survey MCS score (range, 0-100), PHQ-9 score (range, 0-27), and GAD-7 score (range, 0-21). All 3 outcomes were treated as continuous variables. As outlined in the eText in Supplement 2, an additional series of secondary analyses examined changes in the MCS score, symptom severity, and remission rates among subgroups of individuals, including those who had higher clinically significant levels of baseline symptoms and those who were prescribed each of the 2 different medication classes. All models included fixed effects for time (a continuous variable), treatment arm, and the interaction between the 2 variables (ie, time × treatment arm). A first-order, autoregressive, residual covariance matrix structure was specified for each model. Finally, standardized mean treatment arm differences in the primary and secondary outcomes were calculated at 6-month follow-up to derive effect size estimates.

Results
Sample Characteristics, Bivariant Analyses, and Attrition
Most individuals were prescribed citalopram hydrobromide, sertraline hydrochloride, duloxetine hydrochloride, lorazepam, or alprazolam. There were no treatment arm differences in rates of medication type or dosage. Table 1 lists additional sample characteristics stratified by intervention arm. Individuals randomized to the CM arm were more likely to be female, were less likely to use alcohol, and reported poorer overall MH. An analysis of bivariable correlations among clinical and background characteristics and the 3 main outcome variables revealed that age, poor finances, high-risk suicidal ideation, and a history of depression were each related to at least 1 of the outcome variables (P ≤ .05 for all). Therefore, these variables were included in the subsequent adjusted regression models.

Comparisons of 240 individuals (23.6%) who completed only the baseline interview vs 778 individuals (76.4%) who completed at least 1 follow-up interview showed that those who were lost to attrition were more likely to be male (χ² = 6.25, P = .04) and older (F(2,1015) = 4.16, P = .02) and had higher Blessed Orientation-Memory-Concentration Test scores at baseline (F(2,1015) = 11.05, P < .001). There were no other treatment arm differences, including treatment arm randomization, nursing home placement rates, and death, across those who were lost to attrition and those who completed follow-up interviews.

Outcome Analyses
Overall MH Functioning
Analyses revealed significant main effects for time (β [SE], 0.27 [0.09]; 95% CI, 0.09-0.44; P = .003) and for time × treatment arm, in which individuals in the CM arm reported greater improvements in overall MH functioning over time relative to those in the MA arm (β [SE], 0.36 [0.12]; 95% CI, 0.12-0.60; P = .004) (Table 2 and Figure 2). The text reports β levels (SEs), while the figures show the corresponding means (SDs). The calculated effect size at 6-month follow-up was 0.16 (95% CI, 0.02-0.30), and the number needed to treat was approximately 8.8.

Depressive Symptoms
There was a significant time effect (β [SE], −0.34 [0.04]; 95% CI, −0.42 to −0.26; P < .001) and time × treatment arm effect (β [SE], −0.20 [0.06]; 95% CI, −0.32 to −0.09; P < .001), in which those in the CM arm had greater reductions in depressive symptoms over time relative to those in the MA arm (Table 2 and Figure 3). Secondary outcome measures, including remission rates, confirm the effectiveness of CM relative to MA (eText and eFigures 1, 2, and 3 in Supplement 2). The effect size at 6-month follow-up was 0.24 (95% CI, 0.10-0.39).

Anxiety Symptoms
Significant main effects for time (β [SE], −0.10 [0.03]; 95% CI, −0.17 to −0.03; P = .003) and for time × treatment arm (β [SE], −0.23 [0.05]; 95% CI, −0.33 to −0.14; P < .001) were observed for the entire sample when examining change in the GAD-7 scores over time (Table 2 and Figure 3). Specifically, relative to the MA arm, the CM arm showed greater reductions in anxiety symptoms over the course of follow-up. The effect size was 0.28 (95% CI, 0.13-0.43) at 6-month follow-up.

Discussion
The findings herein support the hypothesis that a telephone-delivered, measurement-based, collaborative MH CM program results in better overall MH functioning and greater symptom improvement compared with symptom MA. Compared
with those receiving MA, individuals with moderate to severe baseline symptoms receiving CM also were more likely to achieve remission at follow-up (eText in Supplement 2). The SUSTAIN program is novel in its ability to provide services for a unique sample of vulnerable, geographically dispersed, community-dwelling older adults. The ability to identify, assess, and enroll this subsample of older adults with low refusal rates over time confirms program feasibility and scalability. Both the initial response rate of individuals who received telephone calls for a baseline clinical interview and the retention rate over time are comparable to rates from past work with community-based samples of older adults.4,16,41-45 The few individuals with
severe symptoms requiring specialty MH care and the many individuals with very mild symptoms demonstrate the need for services that differ in focus from specialty care. The inclusion of nonpsychiatric practices beyond primary care is also a novel component and has received limited attention in randomized clinical trials but represents a need when considering population health.

These findings echo the results from prior clinical trials showing that measurement-based, collaborative MH care programs that involve symptom monitoring, intensive CM, and treatment algorithms are effective and associated with positive short-term and long-term outcomes. Validating the symptom-level benefits were improvements in overall MH functioning herein, which were seen despite the short duration of the intervention. These results also support other findings showing that simple symptom MA is not sufficient to fully address mental illness and is most valuable in the context of treatment that includes formal clinical interpretation and structured reaction to symptom monitoring. The results herein also underscore the value of structured MH CM in which individuals are monitored and the information is provided to the prescribing professional as an added resource to primary care and pharmacological management. The observed effect sizes, which were based on a comparison of 2 active treatment arms, are comparable in size to those found by Gilbody and colleagues in their 2006 meta-analytic review of collaborative vs usual care for the treatment of depression and in more recent collaborative care clinical trials, lending further support to the notion that the added benefit of CM is both statistically and clinically relevant. Nonetheless, future work should focus on identifying and enhancing the components of CM that are most beneficial in an effort to improve overall effectiveness. Additional work is also needed to examine the cost-effectiveness and economic implications of these findings from multiple perspectives (ie, consumer, payer, and societal). This type of work would be particularly informative among subgroups of older adults who might be especially vulnerable to mental and physical health issues and increased health care use.

There are limitations to consider when interpreting the program results herein. First, information regarding the indication for the index medication prescription was not available, nor did we take into account additional prescribed psychotropic and nonpsychotropic medications. Furthermore, we did not collect data on adherence to the index medication, which is a potential mediator of treatment arm differences in outcome, during the follow-up assessments. Second, the inclusion criteria for clinically significant symptoms were somewhat broad and spanned multiple symptom domains (eg, depression, anxiety, and suicidal ideation). While the assessment and management of multiple comorbid conditions is a strength of the program, future work may benefit from more in-depth analysis of the relative effectiveness of different treatment strategies among subcategories of individuals. Third, although the 2 treatment arms provided different intensities of intervention and interaction with individuals, there remains...
variability that is unaccounted for in the content of the MH CM telephone calls. Fourth, the intervention effects observed in both treatment arms should be interpreted with some caution given the lack of a control group for comparison and the absence of masking of outcome assessments. Fifth, the results from our analysis may not generalize to other samples of older adults, racial/ethnic minorities, or younger or middle-aged adults with severe MH symptoms. However, because the sample comprised a random sampling of low-income, geographically dispersed, community-dwelling older adults, we believe that they, as a group, represent a unique aspect and strength of the study. Our findings have the potential to directly influence the care of older adults and inform policy decisions regarding the treatment of key consumers, such as current Medicare and Medicaid beneficiaries.

Conclusions

This article summarizes the results from a randomized clinical trial of MH symptom MA vs symptom monitoring plus intensive CM among low-income, community-dwelling older adults. The findings suggest that effective MH CM strategies can be delivered across a large geographical region in a scalable manner using informatics support and available individual data for case finding. Moreover, the study results demonstrate that an enhanced CM program of evidence-based, collaborative care designed to address multiple MH symptoms and non-MH needs and provide access to MH health care professionals is associated with better outcomes compared with symptom MA.

ARTICLE INFORMATION

Submitted for Publication: May 28, 2015; final revision received September 9, 2015; accepted September 12, 2015.


Author Contributions: Drs Mavandadi and Oslin had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Mavandadi, DiFilippo, Streim, Oslin. Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Mavandadi, Oslin. Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Mavandadi, Benson. Obtained funding: Oslin.

Study supervision: Streim, Oslin.

Conflict of Interest Disclosures: None reported.

Funding/Support: This study was supported by the Pharmaceutical Assistance Contract for the Elderly program, Pennsylvania Department of Aging, Harrisburg.

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

Additional Contributions: The following individuals supported the project: Thomas M. Snedden, MPA, and Theresa Brown, MPA (Pharmaceutical Assistance Contract for the Elderly program), Shirley H. Leong, PhD (Corporal Michael J. Crescenz Veterans Affairs Medical Center), and Debra A. Keller, PhD, MPH, Jian Ding, PhD, and Leroy Latty, AB (all with Magellan Health, Inc.).

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