

Effects of Problem-Solving Therapy and Clinical Case Management on Disability in Low-Income Older Adults

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Objective: To test the following hypotheses: (1) Clinical case management integrated with problem-solving therapy (CM-PST) is more effective than clinical case management alone (CM) in improving functional outcomes in disabled, impoverished patients and (2) improvement in depression, self-efficacy, and problem-solving skills mediates improvement of disability. **Methods:** Using a randomized controlled trial with a parallel design, 271 individuals were screened and 171 were randomized to 12 weekly sessions of either CM or CM-PST at 1:1 ratio. Raters were blind to patients' assignments. Participants were at least age 60 years with major depression, had at least one disability, were eligible for home-based meals services, and had income no more than 30% of their counties' median. The WHO Disability Assessment Scale was used. **Results:** Both interventions resulted in improved functioning by 12 weeks ($t = 4.28$, $df = 554$, $p = 0.001$), which was maintained until 24 weeks. Contrary to hypothesis, CM was noninferior to CM-PST (one-sided $p = 0.0003$, $t = -3.5$, $df = 558$). Change in disability was not affected by baseline depression severity, cognitive function, or number of unmet social service needs. Improvements in self efficacy ($t = -2.45$, $df = 672$, $p = 0.021$), problem-solving skill ($t = -2.44$, $df = 546$, $p = 0.015$), and depression symptoms ($t = 2.25$, $df = 672$, $p = .025$) by week 9 predicted improvement in function across groups by week 12. **Conclusion:** CM is noninferior to CM-PST for late-life depression in low-income populations. The effect of these interventions occur early, with benefits in functional status maintained as long as 24 weeks after treatment initiation (clinicaltrials.gov; NCT00540865). (Am J Geriatr Psychiatry 2015; 23:1307–1314)

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INTRODUCTION

Disability in older adults is a major public health concern with numerous causes, the most common being depression.^{1,2} In 2012, the World Health Organization (WHO) listed depression as the leading source of disability globally and a major contributor to disease burden worldwide.³ Studies in older adults show that the likelihood of becoming disabled increases with each new symptom of depression and that the likelihood of recovering from a disability decreases as depression symptoms increase.^{4,5} This is particularly true for older adults living in poverty. The number of older adults living in poverty is high, with 8.1% of U.S. adults aged 65–74 and 10% of those over 75 living below the official poverty line.⁶ Older adults living in poverty are 2.6 times more likely to suffer from depression than middle-income older adults and are more likely to be disabled as a consequence.^{7–10} The comorbidity of depression and disability in low-income older adults is high^{11,12} and increases the cost of healthcare in the United States. These costs are largely due to the disabling effects of depression¹³ and could be reduced if depression and the accompanying disability were treated effectively.^{14–17}

A number of studies demonstrated the effect of depression treatment on disability in healthy older adults,^{18,19} yet few large-scale clinical trials have investigated the impact of depression treatments on disability in low-income adults with physical limitations. A complexity of treating depression in low-income older adults is the limited access and acceptability of depression treatment. Low-income older adults prefer counseling-based interventions to medication management^{20,21} and when treated with medications show poor compliance^{22–24} and poor outcomes.²⁵ Psychotherapy, although preferred by this population, is limited in its availability and in its ability to address the social needs of people living in poverty.^{26,27} Disabled, impoverished older adults experience numerous social and environmental stressors that require case management (CM) interventions to address unmet needs in a way that antidepressants and psychotherapy cannot.^{27–30} Although psychotherapy may address disability through resolution of the depressive syndrome, CM has the potential to augment this effect by linking disabled, impoverished elders to social, medical, and

rehabilitative services that may directly address behavioral and physical limitations.^{30–32}

Given the preference for psychotherapies and the need for CM services, we developed an intervention that combines problem-solving therapy (PST)³³ with clinical CM.²⁷ Our decision to combine these two interventions was based on their potential synergy. We conceptualized CM as an intervention that provides access to social and medical resources and entitlements. Accordingly, it creates an environment in which a person with disability can maximize his or her function and reduce the experience of stress. CM has a beneficial effect on disability in adults.³⁴ PST can provide patients with the skills to use the resources made available by CM by setting goals and developing strategies to meet these goals on their own. Thus, we reasoned that combining CM with PST (CM-PST) has the best chance to reduce disability by providing access to much needed financial, social, and medical resources and by helping impoverished, depressed, disabled older adults develop the skills to use them. Based on the same reasoning, we further hypothesized that the advantage of CM-PST over CM alone in reducing disability would be mediated by reduction in depression and improvement in problem-solving skills and self-efficacy.

We already reported in this journal that CM was noninferior to CM-PST in reducing depression in a sample of disabled, impoverished, older adults with major depression.³⁵ This is the first report on the primary hypothesis of this study comparing the efficacy of CM-PST to that of CM alone in reducing disability. Further analyses examined whether change in depression severity, problem-solving skills, and sense of self-efficacy during this trial influenced disability at the end of the trial. Finally, we examined the moderating effects of unmet social service needs, depression severity, and cognitive functioning before treatment on differences in efficacy between interventions to determine for whom these treatments may be most effective.

METHODS

Participants

Participants were recruited from neighboring home-based meals programs near the two research sites, the Weill Cornell Institute of Geriatric

Psychiatry and the University of California, San Francisco. Participants had been receiving unstructured CM as part of their membership in the home-based meals program and were referred to the study by their social workers. Study procedures were approved by the institutional review boards of both universities, and all participants completed an informed consent. Participants were informed that this was a study comparing the effects of two treatments on depression and disability in older adults. All baseline and follow-up assessments were conducted in person, as were all therapy sessions.

Eligibility criteria were as follows: age at least 60 years, participation in a home-delivered meals service, at least one impaired instrumental activity of daily living (assessed using the multilevel assessment instrument),³⁶ low-income defined by the U.S. Department of Housing and Urban Development as extreme financial strain (30% of the local median income), at least one unmet social service need on the Camberwell Assessment of Need for the Elderly (CANE; e.g., access to healthcare, transportation, social services, entitlements, meals, need for in-home support),^{37,38} diagnosis for unipolar major depression (defined by Structured Clinical Interview for *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* [SCID and DSM-IV]),³⁹ 24-item Hamilton Depression Rating Scale (HAM-D)⁴⁰ score ≥ 19 , and absence of other comorbid psychiatric disorders except generalized anxiety disorder (defined by SCID). Candidates were excluded if they intended to attempt suicide in near future, had antisocial personality, had a Mini-Mental State Exam (MMSE)⁴¹ score ≤ 24 or dementia defined by DSM-IV, could not speak English, were receiving psychotherapy, or planned to start a new antidepressant or change their antidepressant's dose.

Interventions

Training and Fidelity. Twelve licensed clinical social workers were trained by experts to provide CM-PST and CM. Training consisted of a 2-day workshop to review treatment manuals and to engage in simulated case practice. Each therapist then treated three practice cases. Their sessions were audiotaped and reviewed by supervisors for certification. The training cases were not included in the final analyses. Therapists were monitored regularly

for treatment fidelity by independent raters using the PST provider adherence checklist for the PST-CM condition and the CM adherence checklist for the CM condition. Clinicians were given corrective feedback if any session fell below 4 (very good), and any therapist who did not maintain an average adherence score of 4 was excluded from the study ($N = 2$). Monthly supervision was provided for each intervention, with Dr. Areán (UCSF) and Dr. Raue (Cornell) providing CM-PST supervision and Ms. Dwyer providing CM supervision. Therapists provided treatment in the participants' homes.

Case Management. The CM intervention used for this study is based on the clinical CM manual for older adults with mental health problems developed for the San Francisco County Department of Mental Health, adapted for research ([Appendix 1](#); available online).³² CM begins with an assessment of participant's social service needs and how well those needs are being met using the CANE. Based on the assessment, therapists develop a plan to link participants to social and medical services. Therapists also act as advocates for participants in situations where participants cannot advocate effectively for themselves. To control for contact effects with CM-PST, therapists met weekly with participants randomized to CM for 12 weeks and were instructed not to engage in any other interventions.

Case Management and Problem-Solving Therapy. CM-PST is a combination of the CM intervention described above and PST.²⁷ In the first session, therapists conduct a needs assessment and educate participants about problem-solving treatment. Therapists then create a problem list and, with the help of participants, divide problems into those that therapists will solve through CM and those that participants can solve using PST. In later sessions, therapists demonstrate how PST works on specific problems and train participants to use the PST approach for problems they are able to solve. In follow-up sessions, therapists check in on participant progress in solving their own problems, help participants solve new problems, and update participants about CM problems.

Blinding

Research assistants were blind to treatment assignment. Psychotherapy trials makes blinding therapists to treatment conditions difficult. However,

therapists were unaware of our hypotheses and had separate meetings from the rest of the research team.

Assessment

Eligibility Assessment. Trained research assistants administered the SCID-revised (SCID-R), HAM-D, MMSE, CANE, and the multilevel assessment instrument. These data were then reviewed by two clinician investigators to determine eligibility.

Primary Outcome. Disability, our primary outcome, was determined using the total score on the WHO Disability Assessment Scale II (WHODAS).⁴² We selected the WHODAS as the outcome measure for disability because it treats all disorders at parity when determining level of functioning and has been validated in populations across the age span and across cultures.^{30,43–50} The WHODAS is an interviewer-administered instrument that combines information from participant self-report and interviewer observation to assess six functional domains: understanding and communicating, getting around, self-care, getting along with others, household and work activities, and participation in society. The WHODAS was administered at baseline and at 6, 9, 12, and 24 weeks. Participants were asked to report on their function in these domains over the course of 3 weeks. This method of assessment is reliable and has been used in depression studies.^{5,51}

Other Assessments. We assessed the mediation and/or prediction effects on disability, of severity of depression (HAM-D), problem-solving skills, and self-efficacy. Problem-solving skills were measured with the Brief COPE,⁵² which consists of active coping, planning, positive reframing, denial, and behavioral disengagement domains. Self-efficacy was measured using the General Perceived Self Efficacy Scale (GPSE), a measure of beliefs related to solving new and complex tasks validated and normed in medical and in older populations.⁵³ The Brief COPE and the GPSE were administered at baseline and at 12 weeks.

Power Analysis

We conducted power analysis to determine the optimal sample size needed to detect a clinically meaningful difference in disability between the two interventions. Using an effect size of 0.35, a two-tailed test with $\alpha = 0.05$, power = 0.8, an intraclass correlation coefficient of 0.50, and six follow-up

assessments, we determined that a total of 160 participants (80 per condition) was adequate to test our primary hypotheses. To determine our ability to accurately test mediation effects, we also found that 80 participants per group would exceed 80% power to detect a 5% change in R^2 in the proposed mediators.

Data Analysis

Using mixed-effects models for longitudinal data to account for repeated measurements over time and applying Kenward-Roger adjustments to the denominator degrees of freedom to improve small sample performance, we compared response profiles of disability (baseline and 12 and 24 weeks) between the two treatment conditions. We also examined whether CM was noninferior to CM-PST in its effect on disability (WHODAS) from baseline to week 12, a common process in clinical trials when intervention superiority is not found.^{54–56} We used a noninferiority margin of five-point change in WHODAS (measured on a scale of 0–100) based on Agency for Healthcare Research and Quality recommendations for determining the minimum important difference in clinical trials.⁵⁷

All analyses were intention-to-treat. The mixed-effects models included time effects, treatment group, site, site–treatment interaction, and time–treatment interaction. Three predictor analyses were conducted using lagged values of the Brief COPE, GPSE, and HAM-D scores over 12 weeks. Moderation was assessed by checking the interaction of baseline depression, MMSE, and unmet need with treatment effects in the mixed-effects model described above. Analyses were conducted using SAS (version 9.1; SAS Institute, Cary, NC).

RESULTS

Participant Flow and Sample Characteristics

An initial 271 participants were screened for eligibility, 187 of whom met study criteria. Of these, 171 were consented and randomized: 87 participants were randomized to CM and 84 to CM-PST. Of the final sample, 88% (N = 150) completed the 12-week assessment. There was no significant difference in drop-out between the two conditions (CM: 9; CM-PST: 12). Most participants attended all

treatment sessions, with 93% in CM and 91% in CM-PST completing all sessions (Fig. 1).

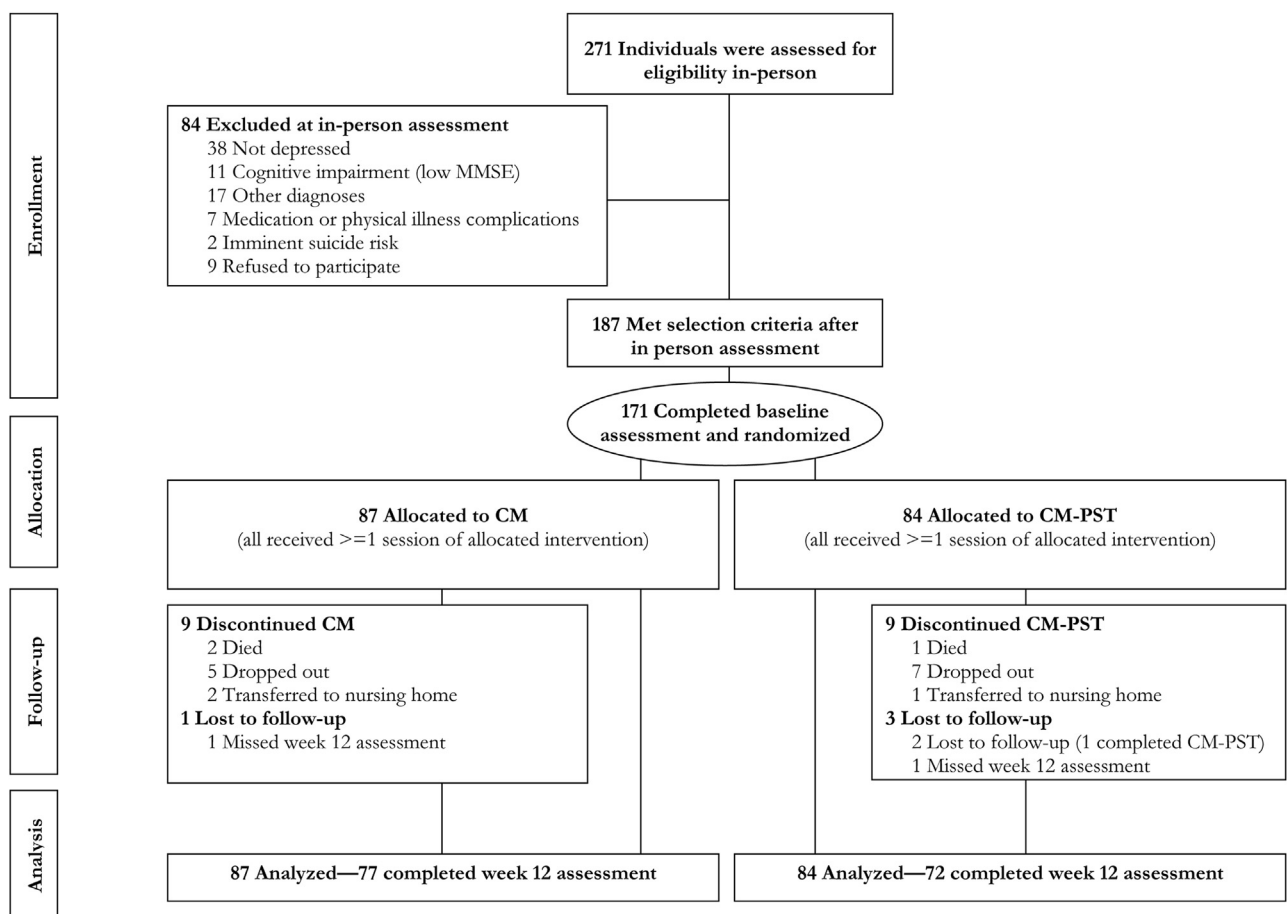
The demographic characteristics of the sample were published previously.³⁵ Participants were on average 74.9 years old (standard deviation [SD]: 9.3) and had slightly above high school educations, with an average of 13.2 years (SD: 2.9) of schooling. They were moderately depressed (mean HAM-D score = 23) and had an average of 4.6 unmet social service needs. Preliminary analyses found no significant differences between conditions or sites on age, education, social service needs, or depression severity. This was a moderately disabled population as determined by baseline WHODAS scores (mean: 34; SD: 7.4); scores of 25–49 correspond to moderate disability.⁵⁸ Although the sample all met criteria for major depression, 26% received antidepressants at

therapeutic dosages and less than 21% were taking benzodiazepines or sleep aides; no one was taking a cognitive enhancer. There were no significant differences in demographics, depression severity, or disability between participants who had been on antidepressants and those who had not.

Outcomes

Changes in Disability. Analyses found a 3.8-point improvement in disability for the whole sample from baseline to week 12 ($t = 4.28$, $df = 554$, $p < 0.0001$). Change in disability occurred quickly, with a 3.32-point improvement in disability by week 3 ($t = -4.26$, $df = 601$, $p < 0.0001$). We found no changes in disability scores between 12 and 24 weeks ($t = 0.16$, $df = 708$, $p = 0.87$) (Fig. 2).

FIGURE 1. Flow of subjects into the treatment trial.



CM-PST vs. CM for Late-Life Disability

Outcomes between the two interventions were similar over time. Participants in the CM condition showed a smaller improvement in disability (a 2.6-point change from baseline to week 12) than the CM-PST group (a 3.8-change from baseline to week 12), but this was not a statistically significant difference (estimated difference: 1.3; 95% confidence interval: -0.8 to 3.4 ; $p = 0.23$, $t = 1.2$, $df = 558$). Because the upper end of the confidence interval was 3.4 , we can assert that CM is noninferior to CM-PST using the noninferiority margin of 5 (one-sided $p = 0.0003$, $t = -3.5$, $df = 558$).

Baseline Predictors of 12-week Outcome. Our original intention for this study was to investigate potential moderators of treatment response. However, because we found no treatment differences, we investigated pretreatment/baseline predictors of 12-week disability for the whole sample. In particular, we were interested in determining if number of unmet needs, severity of depression, and cognitive function predicted outcomes. We found that none of these baseline characteristics was associated with treatment outcome. People with large numbers of unmet needs did as well as people with only a few unmet needs ($F = 1.70$, $df = 5, 545$, $p = 0.38$), and participants with more severe depression at baseline improved as much as those with moderate levels of depression ($F = 0.55$, $df = 5, 570$, $p = 0.70$). Likewise, there was no effect of cognitive function on 12-week disability ($F = 2.03$, $df = 5, 545$, $p = 0.074$).

Change-Related Predictors of 12-week Outcome. This study was originally designed to test mediation effects of the difference in efficacy of CM-PST versus CM. However, mediation analysis would not be meaningful because the efficacy of CM was statistically indistinguishable from that of CM-PST. For this

reason, we examined whether change in variables initially hypothesized as mediators predicted 12-week disability scores in the entire sample. A mixed-effects model demonstrated that change from baseline to 9 weeks in self-efficacy ($t = -2.25$, $df = 672$, $p < 0.021$), problem solving ($t = -2.44$, $df = 546$, $p = 0.015$), and depression severity ($t = 2.50$, $df = 672$, $p < 0.025$) predicted the level of disability at 12 weeks.

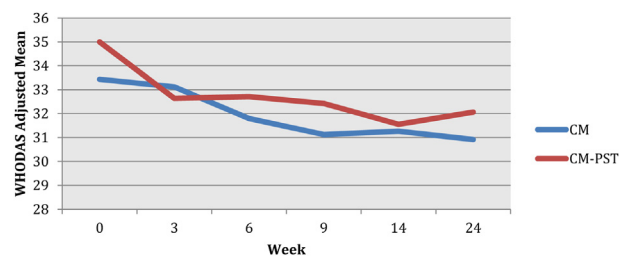
DISCUSSION

This study failed to demonstrate superiority of CM-PST over CM in improving disability. Its most important finding was that after 12 weeks of CM, either alone or combined with PST, participants experienced significant improvements in function and were able to maintain their improvement for an additional 12 weeks after treatment ended. It is important to highlight that the improvement in disability in both treatments arms was both statistically and clinically significant. Moreover, the benefits occurred rapidly, with marked improvement in functioning seen as early as 3 weeks into treatment.

The absence of differences between interventions on disability suggests that functional improvement was largely driven by the CM intervention. Improvement in depression, problem-solving skill development, and increased self-efficacy (i.e., the belief in one's ability to achieve personal goals) predicted changes in disability over time across conditions. These findings are consistent with studies in medically compromised but nondepressed populations, where assistance with negotiating complex healthcare systems and managing chronic illnesses results in better well-being, sense of self-efficacy, and overall functioning.^{59–61} Although CM does not explicitly address psychopathology, problem-solving, and self-efficacy, it is likely that when case managers address problems that feel overwhelming to depressed, disabled, low-income older adults, patients see that change is possible and learn the process of solving these problems by observing their case managers solve them.

This study's findings should be viewed in the context of its limitations. Participants in both conditions received CM, and we did not include arms of PST alone, unstructured CM, or usual care; the study's CM was structured and offered by trained therapists whose quality of care was monitored.

FIGURE 2. WHODAS changes over time (adjusted means): CM versus CM-PST.



Therefore, it is unclear how the study's structured CM efficacy compares with PST alone, unstructured CM, usual care, or passage of time. However, all participants had received unstructured CM by social workers of the home-delivered services and had failed to respond, as shown by the presence of major depression at study entry. Another limitation is the absence of a performance measure of disability. However, the WHODAS is based on both patient self-report and rater observation and was developed to capture the WHO concept of disability that encompasses physical and behavioral components.

We find it encouraging that CM is noninferior to the more complex CM-PST in reducing disability in depressed, disabled, low-income older adults. Psychotherapies are often too difficult for frontline workers to learn and sustain,⁶² and psychotherapies are rarely used with fidelity in social service settings.²⁶ CM is an intervention that most social service workers are trained to provide. Interventions and outcomes of CM are measurable (e.g., linkage to services, improved

functioning) and consistent with the Affordable Care and the Mental Health Parity and Addiction Equity Acts. Demonstrating that CM can reduce disability in a sick and often neglected older population provides a reason for community-based social services to offer training and supervision in structured CM so it can reach the many impoverished, depressed, disabled older adults in need of care.

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