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# Clinical Case Management versus Case Management with Problem-Solving Therapy in Low-Income, Disabled Elders with Major Depression: A Randomized Clinical Trial

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### **Abstract**

**Objective**—To test the hypotheses that (1) clinical case management integrated with problem-solving therapy (CM-PST) is more effective than clinical case management alone (CM) in reducing depressive symptoms of depressed, disabled, impoverished patients and that (2) development of problem-solving skills mediates improvement of depression.

**Methods**—This randomized clinical trial with a parallel design allocated participants to CM or CM-PST at 1:1 ratio. Raters were blind to patients' assignments. Two hundred seventy-one individuals were screened and 171 were randomized to 12 weekly sessions of either CM or CM-PST. Participants were at least 60 years old with major depression measured with the 24-item Hamilton Depression Rating Scale (HAM-D), had at least one disability, were eligible for home-based meals services, and had income no more than 30% of their counties' median.

**Results**—CM and CM-PST led to similar declines in HAM-D over 12 weeks (t = 0.37, df = 547, p = 0.71); CM was noninferior to CM-PST. The entire study group (CM plus CM-PST) had a 9.6-point decline in HAM-D (t = 18.7, df = 547, p <0.0001). The response (42.5% versus 33.3%) and remission (37.9% versus 31.0%) rates were similar ( $\chi^2$  = 1.5, df = 1, p = 0.22 and  $\chi^2$  = 0.9, df = 1, p = 0.34, respectively). Development of problem-solving skills did not mediate treatment outcomes. There was no significant increase in depression between the end of interventions and 12 weeks later (0.7 HAM-D point increase) (t = 1.36, df = 719, p = 0.17).

**Conclusion**—Organizations offering CM are available across the nation. With training in CM, their social workers can serve the many depressed, disabled, low-income patients, most of whom have poor response to antidepressants even when combined with psychotherapy.

#### Keywords

Case management; low income; late-life depression

#### INTRODUCTION

The Institute of Medicine anticipates that the "silver tsunami" of older adults will overwhelm the mental health workforce, and their needs can only be met by changing models of care. Most vulnerable among them are the 9.5% of elders who live in poverty. Low-income elders have higher rates of major depression (9%) than nonimpoverished older adults (3.8%). Their depressive symptoms worsen their already high medical burden and disability 4,5 and increase mortality.

Most depressed, impoverished, older adults have poor outcomes. Depression in low-income elders has unfavorable response to antidepressants even when combined with psychotherapy. One reason for poor response may be the daily exposure to "real-life" stressors: living in high-crime neighborhoods, none—handicap accessible and often infested apartments, limited access to healthcare, isolation, and living with the restrictions of limited finances.

Case management (CM) offers access to resources and can improve the daily experience of low-income older adults. Many types of CM exist. Clinical CM in particular offers financial, legal, and housing resources; linkage to care; and psychoeducation. Of CM can improve the process of care and reduce symptoms of depression, disability, and institutionalization. For these reasons arguably, CM may reduce depression in low-income, disabled, older adults.

Case managers problem-solve for their clients but do not directly teach them skills needed to use newly available resources. For this reason, we integrated CM with problem-solving therapy (CM-PST). PST is efficacious in late-life major depression<sup>13–15</sup> and can enhance problem-solving skills.<sup>16</sup> Thus, PST may act in synergy with CM, with CM providing access to resources and PST imparting the skills needed for their utilization.

This study compared the efficacy of home-offered CM with that of CM-PST in low-income elders with major depression and disability receiving home-delivered meals services. Its first hypothesis postulates that CM-PST is more effective than CM in reducing depressive symptoms over 12 weeks. The second hypothesis is that problem-solving skills development mediates improvement of depression. Additional analyses compared the stability of improvement in depressive symptoms 12 weeks after the end of the intervention. We also compared response and remission of depression at intervention end and 12 weeks later. Finally, we explored whether improvement in depression was related to reduction in unmet social needs over 12 and 24 weeks.

### **METHODS**

This randomized clinical trial used a parallel design to compare depression severity in participants allocated to CM or CM-PST at a 1:1 ratio.

## **Participants**

Social workers of home-delivered meals organizations offering unstructured CM referred potential participants if they considered them to be depressed. All subjects signed written informed consent. Procedures were approved by the institutional reviews boards of both universities.

Inclusion criteria were (1) age 60 or more years, (2) recipients of home-delivered meals services with at least one impaired instrumental activity of daily living, <sup>17</sup> (3) major depression defined by the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV), <sup>18</sup> (4) 24-item Hamilton Depression Rating Scale (HAM-D)<sup>19</sup> 19, (5) income no more than 30% of the area median, (6) at least one unmet services need (Camberwell Assessment of Need for the Elderly [CANE]), <sup>20,21</sup> and (7) agreement to not start antidepressants or if on an antidepressant not to change the dosage. Exclusion criteria were (1) presence or history of any Axis I psychiatric disorder other than nonpsychotic major depression or generalized anxiety disorder; (2) intent or plan to attempt suicide in near future; (3) antisocial personality (defined by DSM-IV); (4) Mini-Mental State Exam score < 24 or dementia defined by DSM-IV; (5) delirium, metastatic cancer, decompensated organ failure, major surgery, stroke, or myocardial infarction 3 months before entry or taking drugs known to cause depression; (6) currently in psychotherapy; (7) inability to perform any activity of daily living, even with assistance; and (8) inability to speak English.

#### Randomization and Masking

Participants were assigned to CM or CM-PST by the investigators within each site using random numbers in blocks of six participants generated by the Biostatistics Unit of the Weill Cornell Institute of Geriatric Psychiatry. Raters were unaware of randomization status. Interventionists were aware of randomization status but not of study hypotheses.

#### Interventions

The interventionists were master's level, licensed clinical social workers trained in one of the two interventions.

**Case management**—CM consisted of twelve 1-hour meetings focusing on needs assessment using the CANE, <sup>20,21</sup> education about depression, service planning, linkage to social services, help accessing health-care, advocacy, and exploration of barriers perpetuating needs. CM managers were directed not to teach problem-solving skills. Linkage to social, health, rehabilitation, and transportation services and advocacy with financial services occurred between sessions and occasionally involved caregivers and providers.

Training consisted of the CM manual presentation (Supplementary Appendix 1; available online), discussion of a videotape of CM meetings, and role-playing. Then, CM managers conducted practice interventions with at least three individuals. Sessions were audiotaped and rated by the CM trainer with the CM Adherence form, which consists of three domains: needs assessment, intervention planning, and encouragement of service use. CM managers were required to receive an average score of 4 ("good") in three consecutive cases.

Intervention fidelity was assessed by the CM trainer (Eleanor Dwyer, LCSW) who evaluated the first, sixth, and last audiotaped sessions of half the participants using the CM Adherence form. We used the Use of Proscribed Interventions Scale to ensure no formal psychotherapeutic techniques were used. The CM trainer provided feedback to CM managers during monthly telephone supervision. Independent assessment of fidelity to CM consisted of evaluations of 10% of CM tapes by a CM expert (Robert Surber, LCSW) unrelated to the study team.

**An illustrative CM case**—Ms. A, a 76-year-old widow, suffered from depression, diabetes, hypertension, retinopathy, peripheral neuropathy, and toe ulcers. Her only income was social security. She had difficulty leaving her apartment because of debilitation, pain in her feet, and poor eyesight. Since her daughter moved out of state, Ms. A had stopped seeing her physician and had been taking half doses of her medications to reduce copayment. Ms. A had been receiving distressing notices for unpaid bills.

The home-delivered meals social worker recognized her depression and referred her to the study. Her HAM-D was 28. A CM manager visited Ms. A at home and explained that some of her feelings and thoughts were a result of depression, a medical disorder. The CM manager enlisted her in a transportation service, which enabled her to go to medical appointments and to a senior citizens center. The CM manager called Ms. A's primary care physician who substituted Ms. A's medication with generic drugs where possible. The CM manager registered Ms. A in financial relief programs with companies producing two of her nongeneric medications. Ms. A had her toe ulcers attended to by a podiatrist and reduced her discomfort while walking. Ms. A and the CM manager contacted Ms. A's daughter, who helped Ms. A to set up a plan for paying bills. With her finances in better order, Ms. A continued to see her physician; she had avoided him because she had felt unable to afford her medication. She began meeting her old friends and found them welcoming, supportive, and understanding of her absence over the previous months. With improved medical monitoring, her diabetes and hypertension were better controlled. Her depression subsided (HAM-D = 8 at 12 weeks). Had Ms. A been assigned to CM-PST, in addition to CM, she would have also been trained in the PST process and practiced her PST skills in planning, scheduling, preparing, and pursuing her medical visits and social activities.

Case management with problem-solving therapy—CM-PST consists of the CM components and training in the steps of the PST process: define a problem, set a goal, brainstorm ideas to solve the problem, select a solution, and create an action plan. The patient then uses the PST approach to solve specific problems. The CM-PST manager addresses social problems beyond the patient's ability to solve.

Training consisted of review of the CM-PST manual (Supplementary Appendix 2; available online), discussion of videotaped CM-PST sessions, and role-playing of typical sessions. CM-PST managers treated at least three practice cases. These cases were audiotaped and reviewed by PAA or PJR with a standardized CM-PST Adherence form. Managers were required to achieve an average score of 4 ("good") in at least three consecutive cases.

Fidelity to CM-PST was assessed by the CM-PST trainers (PAA and PJR), who evaluated the first, sixth, and last audiotaped sessions of half of the participants using the CM-PST Adherence form. The CM-PST trainers provided feedback to the interventionists during monthly telephone supervision. An independent assessment of fidelity to the CM-PST intervention consisted of evaluations of 10% of the CM-PST tapes by an expert (Rebecca Shermer, Ph.D.) unrelated to the study team.

#### **Assessment and Outcomes**

Diagnosis was assigned by agreement of two clinicians after review of history, Structured Clinical Interview for DSM-IV, and other ratings. The primary outcome was the 24-item HAM-D.<sup>19</sup> Need for social services was evaluated with the CANE. The Social Problem Solving Inventory-Revised<sup>22</sup> did not capture the problem-solving skills of our participants. For this reason, we used five domains of the Brief COPE:<sup>23</sup> active coping, planning, positive reframing, denial, and behavioral disengagement. Disability,<sup>24</sup> medical burden,<sup>25</sup> overall cognitive impairment,<sup>26</sup> verbal memory,<sup>27</sup> and executive functions,<sup>28–30</sup> were also assessed.

The HAM-D and World Health Organization Assessment Schedule-II (WHODAS)<sup>24</sup> were assessed at baseline and at 3, 6, 9, 12, and 24 weeks. The CANE and COPE were administered at baseline and at 9, 12, and 24 weeks; their values were not expected to change sooner than these times.

#### **Data Analysis**

Power analyses for comparisons of depression severity were based on an algorithm for mixed-effects linear regression. Eighty participants per group were sufficient for a standardized effect size of 0.35, two-tailed  $\alpha=0.05$ , power = 0.86 postrandomization observations, and intraclass correlation coefficient of 0.50. We used the Power and Precision software for power analyses of the mediation hypothesis. Assuming the intervention would account for 10% of HAM-D variance postintervention (after adjusting for covariates), 80 participants per group would exceed 80% power to detect a 5% increment in  $R^2$  accounted for by the mediator.

All participants who completed baseline assessments were included in the intent-to-treat analyses. Profiles of baseline and weekly HAM-D scores over 12 weeks during intervention and, separately, between 12 and 24 weeks (after the intervention) were compared between CM and CM-PST using mixed-effects models. Kenward-Roger adjustments to the denominator degrees of freedom were used to improve small sample performance. The models included time effects, intervention group, site, site–intervention interaction, and time–intervention interaction. In addition, we conducted noninferiority analysis based on a margin of two points in the HAM-D scale; this margin is more conservative than the margin of the National Institute for Clinical Excellence, which defines as clinically significant a

drug-placebo difference of three HAM-D points.<sup>33</sup> Noninferiority was concluded if the upper limit of the one-sided 95% confidence interval (CI) for treatment difference was less than 2.

Change in CANE and COPE from baseline to 9 weeks were separately assessed in mediation analyses of HAM-D scores at 12 weeks (end of intervention). COPE and CANE scores at 12 weeks were evaluated in separate mediation analyses of HAM-D scores at 24 weeks (end of follow-up). Moderation was assessed by checking the interaction of baseline variables with intervention effects in the mixed-effects model described above. Response was defined as a reduction of at least 50% in HAM-D from baseline to 12 or 24 weeks and remission as HAM-D 10 at 12 or 24 weeks. Response and remission were analyzed using  $\chi^2$  analysis. Analyses were conducted using SAS, version 9.1 (SAS Institute, Cary, NC).

#### **RESULTS**

#### Participant Flow

The study screened 271 older persons identified as depressed by social workers providing services as part of home-delivered meals programs (Fig. 1). Of these, 187 individuals met selection criteria; 171 completed the baseline assessment and were randomized to CM (N = 87) or CM-PST (N = 84). Of the 171 participants, 150 (88%) completed the 12-week trial and 12-week assessment. The CM group attended an average of 11.1 (standard deviation [SD]: 2.6) sessions and the CM-PST group 11.0 sessions (SD: 2.9), which were, respectively, 93% and 91% of all sessions. The median number of sessions for each group was 12.

## **Participant Characteristics**

Randomized participants (N = 171) were aged 74.9 years (SD: 9.3) and had 13.2 years (SD: 2.9) of education (Table 1). They experienced moderate depression and had an average of 4.6 unmet social service needs. Their disability and executive function scores were in the mild to moderate severity range. At entry and while they met criteria for major depression, 37% of participants (64/171) were on antidepressants and 27% (46/171) were on therapeutic dosages. Participants on inadequate dosages were receiving imipra-mine (N = 1, 40 mg), amitriptyline (N = 1, 50 mg), bupropion (N = 2; mean: 112 mg; range: 75–150 mg), citalopram (N = 2, 10 mg), duloxetine (N = 4; mean: 25 mg; range: 20–30 mg), venlafaxine (N = 3, 75 mg), mirtazapine (N = 2, 15 mg), paroxetine (N = 1, 10 mg), sertraline (N = 1, 25 mg), and trazodone (N = 1, 150 mg). There were no significant differences in=demographic or clinical variables between participants who were on antidepressants at entry and those who were not. Only four participants on subtherapeutic dosages at baseline increased their dosages into the therapeutic range during the study. Twenty-one percent (36/171) were on benzodiazepines or sleep aids. No one was taking a cognitive enhancer.

#### **Outcomes**

**Depression during the intervention (0–12 weeks)**—A mixed-effects model consisting of intervention group, time, site (Cornell versus University of California San Francisco), and intervention by time interaction as fixed effects and random effects for

intercept and slope showed no difference in HAM-D decline from baseline to 12 weeks between CM and CM-PST (t = 0.40, df = 543, p = 0.69) (Fig. 2). Improvement in HAM-D from baseline to end of treatment was higher in CM-PST (9.86 points) compared with CM (9.45 points). This difference (CM versus CM-PST: -0.41; 95% one-sided CI [ $-\infty$ , 1.30]) indicated noninferiority of CM based on a margin of two HAM-D points and  $\alpha$  = 5%.

The entire study group (CM plus CM-PST) showed a 9.6-point decline in HAM-D during the intervention (t=18.7, df=547, p<0.0001). There were changes of 5.5 HAM-D points by week 3, 6.6 by week 6, and 8.6 by week 9. Site did not significantly contribute to HAM-D variance over time (t=1.8, df=170, p=0.08). Use of antidepressants at therapeutic and subtherapeutic doses did not influence the course of depression (t=1.38, df=145, p=0.17). Further, there was no interaction between therapeutic dosages of antidepressants and intervention assignment ( $\chi^2=0.07$ , df=1, p=0.79).

By the end of the intervention (12 weeks), 42.5% (37/87) met criteria for response (50% decline of baseline HAM-D) to CM and 33.3% (28/84) to CM-PST. Remission rates (HAM-D 10) were 37.9% in the CM group (33/87) and 31.0% in the CM-PST group (26/84). Response ( $\chi^2 = 1.5$ , df = 1, p = 0.22) and remission rates ( $\chi^2 = 0.9$ , df = 1, p = 0.34) were similar in the CM and CM-PST groups.

Exploratory analysis examined baseline predictors of depression (HAM-D) improvement during the 12-week intervention in the entire study group (CM plus CM-PST). Separate mixed-effects analyses showed that only unmet needs (CANE; F = 5.29, df = 161, p = 0.023), disability (WHODAS; F = 13.06, df = 169, p = 0.0004), and history of prior episodes (F = 4.03, df = 163, p = 0.046) were associated with lesser improvement in HAM-D. Chronicity of current depressive episode did not influence remission rates. In the entire study group (CM plus CM-PST), the remission rate of those with duration of episode up to 12 months was 32% (15/47), whereas those with longer episodes had a remission rate of 37% (30/81) at week 12 ( $\chi^2 = 0.17$ , df = 1, p = 0.68).

**Depression 12 weeks after intervention end**—Depression reduction was retained 12 weeks after the end of both interventions. There was no significant change in HAM-D score between the end of interventions and week 24 (0.7-point HAM-D increase) (t = 1.36, df = 719, p = 0.17). There was no difference (t = 0.89, df = 712, df = 0.37) in HAM-D change (baseline to 24 weeks) between CM and CM-PST in a mixed-effects model consisting of intervention group, time, intervention site (Cornell versus University of California San Francisco), and intervention by time interaction.

Twelve weeks after the intervention end, 41.4% (36/87) met criteria for response to CM and 31.0% (26/84) to CM-PST ( $\chi^2=2.01$ , df 1, p = 0.16). The remission rates were 37.9% in the CM group (33/87) and 29.8% in the CM-PST group (25/84) ( $\chi^2=1.27$ , df = 1, p = 0.26).

**Problem-solving, service needs, and disability (0–24 weeks)**—Problem-solving (COPE) improved similarly in both intervention groups (Fig. 3), with no significant mediation effect. In the entire study group (CM plus CM-PST), we constructed a mixed-effects model in which change of COPE from baseline to 9 weeks was used to predict

HAM-D at 12 weeks and change in COPE by 12 weeks was used to predict HAM-D at 24 weeks. The lagged COPE values were associated with subsequent HAM-D values (t < -4.53, df = 491, p <0.0001). A one-point change in COPE led to an estimated reduction of 0.25 in HAM-D (95% CI: 0.14–0.36).

Social service needs (CANE) declined in both groups (Fig. 4). Lagged CANE values defined as above showed no significant association of CANE with subsequent HAM-D values in the two groups (one-point change in CANE led to an estimated change of 0.20 in HAM-D: 95% CI: -0.06-0.45; t = 1.53; df = 504; p = 0.13).

Exploratory analysis examined whether disability (WHODAS) scores of the immediate preceding assessments predicted subsequent depression (HAMD) scores during the intervention phase and 12 weeks after completion. The estimated change in HAM-D for each point change in WHODAS was 0.096 (95% CI: 0.025-0.165; t=2.69; df=719; p=0.0074).

**Moderators of intervention efficacy (0–24 weeks)**—Baseline values of depression, service needs, disability, cognitive impairment (Mini-Mental State Exam), executive functions (Mattis Dementia Rating Scale, initiation/perseveration domain; Stroop Color Word Test; Digit Symbol Substitution), and fluency (Controlled Oral Word Association Test) were not associated with differences in efficacy at 12 and 24 weeks between CM and CM-PST.

#### DISCUSSION

This study failed to demonstrate superiority of CMPST over CM. Its principal finding is that CM was noninferior to CM-PST in the treatment of major depression of impoverished, disabled, older adults. By the end of both interventions, 38% of the entire study group (CM plus CM-PST) met criteria for response and 34.5% for remission. These benefits were retained for 12 weeks after the end of interventions. The salutary effects of CM and CM-PST are important because antidepressants have low efficacy in low-income patients even when combined with psychotherapy.<sup>8</sup>

This is the first study, to our knowledge, to compare two psychosocial interventions in disabled, low-income elders with major depression. Its findings are consistent with earlier reports. In a preliminary study of poor, nondisabled elders with major depression or dysthymia, broadly defined CM alone or in combination with cognitive-behavioral group therapy led to greater improvements in depressive symptoms than cognitive-behavioral group therapy alone. <sup>34</sup> In community-residing elders, support services distinguished persistently depressed from remitted subjects. <sup>35</sup> How-ever, most participants in these studies were not disabled and could access social and clinical services.

This study has limitations. Both groups received CM. Therefore, it is unclear how usual care would have influenced the course of their depression. However, in 63% of participants the duration of their depressive episode was longer than 1 year, and all had received unstructured CM by home-delivered meals organizations but still met criteria for major depression. Moreover, the remission rate of those with depressive episodes 1 year or longer

was comparable with those with shorter episodes. Thus, time and unstructured CM alone may not adequately explain the effect of both interventions. Approximately 37% of participants were on stable dosages of antidepressants (27% on therapeutic dosages), but their depression severity was sufficient for entering the study. Only four patients had an increase in dosage during the study. Therefore, the effect of antidepressants was likely weak.

Contrary to our hypothesis, integrating PST with CM added no benefit, even though PST is effective in depressed older adults. <sup>14,15,36</sup> A potential explanation is that CM was sufficient to reduce depression, leaving little room for further improvement by PST.

Problem-solving skills increased in both the CM and the CM-PST groups (Fig. 3) and predicted subsequent improvement of depression. Mobilization and modeling of CM may have enabled patients to marshal problem-solving skills that had been dormant because of demoralization.

It is encouraging that CM was noninferior than the more complex CM-PST. Effectiveness studies may examine whether CM that provides information to physicians on the status of antidepressant treatment leads to even better outcomes. Organizations offering CM are available. They employ social workers who, with training in this CM model, can serve depressed, disabled, low-income patients. Models of diffusion research<sup>37,38</sup> indicate that attributes of interventions influencing implementation are efficacy, reimbursement, client acceptability, ease of use, cost (time to learn and routinize), compatibility with routine care, observable outcomes, and trialability (can be tested in an organization and dropped at low cost). CM meets these criteria and can be brought to the homes of many depressed, poor, homebound, older persons who otherwise may be left suffering and require hospital care for neglected medical and psychiatric illnesses. Thus, referral to services providing CM may become a treatment alternative for psychiatrists to use for the large number of depressed, impoverished, disabled, older patients for whom classical psychiatric therapies have modest efficacy.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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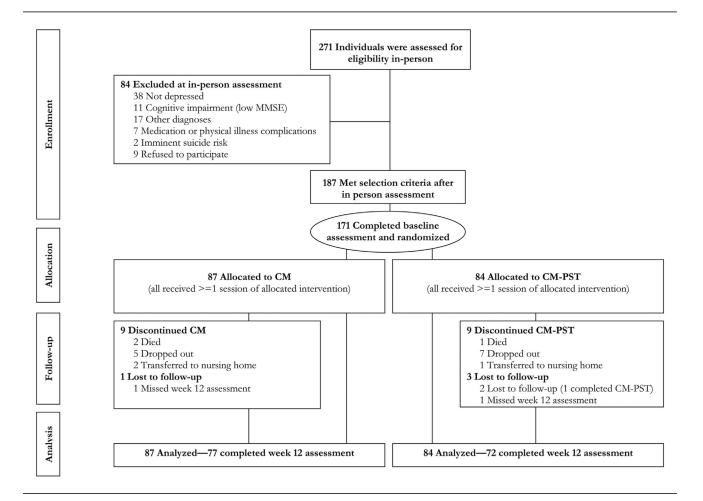
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**FIGURE 1.** Flow of subjects into the treatment trial. MMSE: Mini-Mental State Exam.

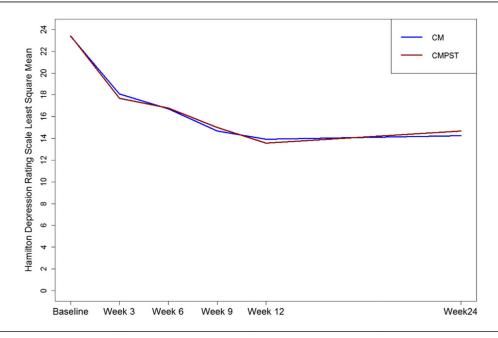
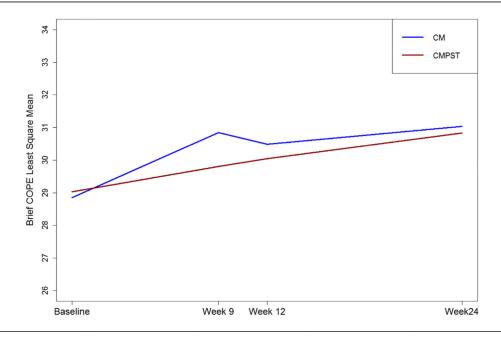


FIGURE 2. Depression severity: CM versus CM-PST.



**FIGURE 3.** Problem-solving skills development (Brief COPE): CM versus CM-PST.

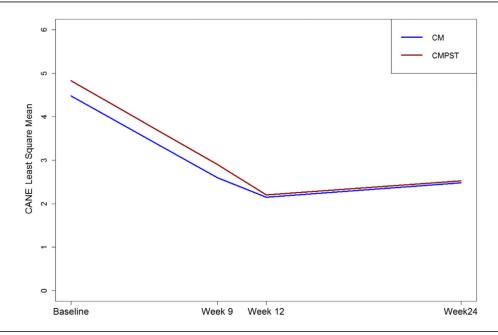


FIGURE 4. Unmet needs change: CM versus CM-PST.

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TABLE 1

Characteristics of Elders with Major Depression Receiving CM (N=87) or CM-PST (N=84)

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Variable	CM		CM-PST		Statistics		
	Mean	SD	Mean	SD	t	df	p
Age, y	74.64	9.00	75.08	9.50	-0.31	169	0.758
Education	13.53	2.84	12.90	2.92	1.43	163	0.155
HAM-D	22.46	4.03	22.74	3.98	.02	169	0.985
Number of previous depressive episodes	2.74	1.79	2.46	1.70	1.01	157	0.314
Length of current depressive episode, months	31.33	37.70	36.32	46.62	-0.75	159	0.455
WHODAS	33.38	7.51	35.00	7.29	-1.42	168	0.158
Charlson Comorbidity Index	3.33	2.14	3.71	2.41	-1.07	167	0.287
Mini-Mental State Exam	27.64	1.79	27.26	1.73	1.36	158	0.176
Hopkins Verbal Learning Test							
Learning correct	17.89	6.64	17.50	4.83	0.41	159	0.680
Recall correct	5.46	3.00	5.57	2.81	-0.23	159	0.816
Executive Functions							
Mattis Dementia Rating Scale, initiation/perseveration domain	32.29	4.87	31.48	5.14	0.99	149	0.322
Stroop Color Word Test	23.73	10.98	20.92	9.44	1.69	150	0.093
Digit Symbol Substitution	29.11	11.66	29.48	11.91	-0.18	127	0.859
Controlled Oral Word Association Test	33.81	15.65	30.23	11.98	1.21	89	0.228
CANE	4.40	2.14	4.83	1.98	-1.36	166	0.177
Brief COPE	28.96	5.75	29.43	5.39	-0.51	147	0.609