Sequential Interventions for Major Depression and Heart Failure Self-Care: A Randomized Clinical Trial

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DATA SUPPLEMENT

Cognitive Behavior Therapy

Supplementary Table S1 describes the dosage of intervention sessions, the reasons for the end of active treatment (i.e., the point at which the frequency of scheduled sessions decreased from weekly to 1-2 times per month), and the extent of CBT homework adherence.

Table S1. Characteristics of the CBT intervention (n = 69).

Characteristic	Mean + SD	Median (IQR)
Number of treatment sessions		
Office	7.4 ± 6.6	6.0 (11.0)
Phone	9.7 ± 7.6	8.0 (10.0)
Total	17.4 ± 7.0	19.0 (9.0)
End of active treatment		
Last week of active treatment	15.5 ± 3.0	16.0 (1.0)
Reason		
Nonadherence	2 (2.9%)	---
Cannot contact	3 (4.4%)	---
Dropped out	5 (7.3%)	---
Logistics	1 (1.5%)	---
Successful completer	13 (18.8%)	---
Timed out @ 16 weeks	44 (63.8%)	---
Died	1 (1.5%)	---
Homework compliance		
Number assigned	14.4 ± 6.9	16.0 (11.0)
Number completed	9.0 ± 5.1	8.0 (7.0)
Percentage completed	58.5 ± 20.7	56.0 (26.4)

Tailored Self-Care (TSC) Intervention

Supplementary Table S2 describes the dosage and delivery modalities of the self-care intervention, as well as reasons for missed visits.

Table S2. Tailored Self-Care (TSC) intervention.

Characteristic	Overall (n = 139)	Group	
		UC (n = 70)	CBT (n = 69)
No. of 'actual' visits	1559 (85.2%)	837 (87.6%)	722 (82.5%)
No. of 'missed' visits	271 (14.8%)	118 (12.4%)	153 (17.5%)
Reason for 'missed' visits			
Cannot contact	106 (39.1%)	49 (41.5%)	57 (37.3%)
Dropped out	3 (1.1%)	1 (0.9%)	2 (1.3%)
Too ill	51 (18.8%)	14 (11.9%)	37 (24.2%)
Logistical barrier	45 (16.6%)	27 (22.9%)	18 (11.8%)
Protocol violation	1 (0.4%)	1 (0.9%)	0 (0.0%)
Other	47 (17.4%)	21 (17.8%)	26 (17.0%)
Refused	12 (4.4%)	0 (0.0%)	12 (7.8%)
Unknown	6 (2.2%)	5 (4.2%)	1 (0.7%)
Mean number of visits			
Office	4.6 ± 4.2	4.5 ± 4.2	4.6 ± 4.3
Phone	6.6 ± 5.0	7.4 ± 4.8	5.8 ± 5.0
Office or phone	11.2 ± 4.2	12.0 ± 3.3	10.5 ± 4.9
Mean session duration per visit (minutes)			
Office	62.2 ± 12.4	63.7 ± 11.6	60.6 ± 13.0
Phone	40.0 ± 11.7	39.8 ± 12.0	40.3 ± 11.4
Office or phone	50.4 ± 10.9	50.4 ± 10.5	50.5 ± 11.4
Mean dosage (hours)			
Office	4.7 ± 4.5	4.8 ± 4.6	4.6 ± 4.5
Phone	4.8 ± 4.5	5.3 ± 4.5	4.3 ± 4.4
Office or phone	9.5 ± 4.3	10.1 ± 3.9	8.9 ± 4.7

Remission of Depression at 16 Weeks

Depression remission rates did not differ between the UC and CBT groups as defined by standard cutoff scores on the BDI-II (20.8% vs. 29.1%; p = 0.26; NNT = 12.0 [11.9, 12.2]) or HAM-D-17 (21.9% vs. 31.4%; p = 0.21; NNT = 10.6 [10.5, 10.8]) scores at 16 weeks.

Moderators of Treatment Effects

The dosage (i.e. number of sessions completed), post-randomization co-interventions, or the number of referrals for outside medical care were added to each primary and secondary statistical model to determine whether these factors affected the outcomes. Preplanned moderator analyses of age, race, baseline severity of depression, and antidepressant use were also conducted. None of these factors moderated the effects of treatment over time. However, referrals for nonstudy care, the dosage of the intervention, age, and female gender were significantly related to depression and anxiety outcomes and as well as to HF self-care maintenance, confidence, and management.

Cointerventions

The research staff and interventionists documented instances in which they recommended that patients seek nonstudy health services. The mean number of recommended actions was higher in the CBT arm (2.7 $\pm$ 2.8) than in the UC arm (0.3 $\pm$ 0.6). The most frequent recommendations were to contact the patient's physician (40%). Receipt of nonstudy health care services was also documented. Health care services involving the patient's physician or a mental health care provider that were documented at the 16-week assessment visit were reported by 74% of the

patients in the usual care arm and 65% of those in the CBT arm. The percentages were similar between groups at the other outcome assessments.

Blinding

Cohen's kappa statistic was used to evaluate whether the outcome assessors were able to identify the participants' group assignments at a level greater than would be expected for random guesses. The agreement between guesses and actual assignments was negligible at 8 weeks ($k=.14$, $p=.11$) and fair at both 16 weeks ($k=.23$, $p=.01$) and 32 weeks ($k=.36$, $p<.0001$). This suggests that the outcome assessors were initially blinded to group assignment, but that the adequacy of blinding may have decreased over time in some cases.

Attrition

A total of 19 (14%) of the patients stopped participating in the study before completing the 32-week assessments. Table S3 displays the reasons for premature study termination.

Table S3. Premature study terminations.

Characteristic	Overall	Treatment Group	
		EUC	CBT
Premature study terminations	19	5 (26.3%)	14 (73.4%)
Reason			
Unable to contact participant	7	2 (40.0%)	5 (35.7%)
Patient refuses further participation	5	1 (20.0%)	4 (28.6%)
Patient died	6	2 (40.0%)	4 (28.6%)
Withdrawn by study staff	1	0 (0.0%)	1 (7.1%)

Note: Proportions are presented as column percentages.