Chapter 12
Cognitive Behavior Therapy for Generalized Anxiety Disorder Among Older Adults in Primary Care: A Randomized Clinical Trial

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Objectives To examine the effects of cognitive behavioral therapy (CBT) relative to enhanced usual care (EUC) in older adults with general anxiety disorder (GAD) in the primary care setting [1].

Methods For this trial, 134 older adults (age 60 years or older) were recruited from 2 primary care settings from March 2004 to August 2006. Participants who scored positive for the two anxiety screening questions from the Primary Care Evaluation of Mental Disorders were further screened using the Structured Clinical Interview for the DSM-IV and Mini-Mental State Examination (MMSE). Those with a principal or coprincipal diagnosis of GAD were included. Individuals who scored less than 24 on the MMSE and had active substance use, psychosis, or bipolar disorder were excluded from this study.

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Primary outcomes consisted of worry severity measured by the Penn State Worry Questionnaire (PSWQ) with a change of 8.5 points demonstrating "meaningful change" and GAD severity measured by the GAD Severity Scale (GADSS) with a change of 2 points being "meaningful." Secondary outcomes included evaluating coexisting anxiety and depression symptoms with the Structured Interview Guide for the Hamilton Anxiety Scale (SIGH-A) and Beck Depression Inventory II (BDI-II), and the physical component score (PCS) and mental component score (MCS) of the 12-Item Medical Outcomes Short Study Form for assessing quality of life. Antianxiety and antidepressant medication use was evaluated based on self-report for the prior 3 months, along with the number of outpatient visits (physical and mental health) to determine if the participants had discussed emotional issues with or received a mental health referral from their primary care physician (PCP).

Participants were treated for 3 months with either CBT or EUC. CBT was provided by therapists for up to ten sessions over 12 weeks, with telephone booster sessions at 4, 7, 10, and 13 months. Therapists were trained in CBT, and 20% of the sessions were independently rated to determine treatment integrity. Participants receiving EUC were telephoned biweekly during the first 3-month interval with support being provided by therapists and notification of the PCP if a participant required immediate psychiatric care. Data collection was conducted via a blinded phone interview, but participants and the therapists were not blinded. Assessments were conducted at baseline, 3 months posttreatment, and over 12 months of follow-up, with assessments at 6, 9, 12, and 15 months. Ten percent of these assessments also had independent raters to determine integrity with the GADSS and SIGH-A and had an intraclass correlation coefficient of 0.99 and 0.95, respectively. Two CBT manual authors evaluated treatment adherence (7.7, range 0–8 [SD, 0.55]) and competence (7.3, range 0–8 [SD, 0.67]). All EUC calls were recorded and twenty percent were reviewed by first author noting only three protocol deviations.

Communication with the PCP occurred through research notes in the written medical record which included diagnoses assigned and reasons for inclusion or exclusion. Participants who were excluded received potential psychiatric referrals. Those participants included in the study had PCP notes encouraging continued care and the designation of the treatment type they were receiving. Of the 134 older adults, 70 were randomized to receive CBT in primary care clinics (mean completed sessions = 7.4), and 64 participants were randomized to receive EUC (mean telephone check-ins = 4.3). At the study midpoint, the EUC group was noted to have a disproportionately large assignment of Hispanic participants, and a stratified randomization schedule was used.

Pre-treatment demographics, clinical characteristics, and medications were compared using a chi-square and t-test. Posttreatment outcomes were compared using the pre-treatment assessment as the covariant. Initial analyses used intention-to-treat (ITT) to address missing data. These were repeated with observed data using a random regression method. Secondary analyses of long-term outcomes used a

repeated-measure analysis of covariance. In order to control for multiple comparisons (primary outcomes, coexisting anxiety-depression, health quality of life), the critical alpha was set as $p < 0.025$ with two-sided significance. Changes in antidepressant and antianxiety medications were analyzed using a chi-square method.

Treatment responders were determined at 3 and 15 months. Those with missing data used for ITT analyses were considered nonresponders. To determine the power needed for this study, scores from the PSWQ were used with a median standard deviation of 10.1. A moderate effect size of Cohen's d = 0.6 (minimal detectable difference 6.2), power of 80%, and alpha = 0.025 was used to determine the study goal of 150 participants to have 53 subjects in each group.

Results Of the 986 referred potential participants, 381 provided consent to participate in the study. Of the 381, 68 individuals dropped out or were excluded prior to the initial diagnostic evaluation due to negative responses on screening questions (14 individuals), lack of interest (35 individuals), or logistic issues (19 individuals). The remaining 313 were assessed for eligibility with 154 individuals excluded for not meeting inclusion criteria and 11 individuals separately grouped as nonclinical training cases not included in analyses. A total of 148 participants met inclusion criteria, and 134 participants (with principal or coprincipal GAD) were randomized after 14 dropped out before this step.

Participants who were randomized had a mean age of 66.9 years [95% confidence interval (CI), 65.9–67.9] and a mean education time of 15.9 years [95% CI, 15.4–16.4] and were likely to be women (75% [105/134], $p = 0.04$) compared to those not randomized. Also, they had a higher baseline PSWQ of 57.2 [95% CI, 55.4–59]. The active treatment phase of 0–3 months had lower dropouts for the CBT group compared to EUC (5.9% [4/70] vs 21.9% [14/64], $p = 0.006$) due to reported dissatisfaction (CBT $n = 0$ vs EUC $n = 9$) with random assignment. Long-term follow-up attrition between 3 and 15 months was comparable for CBT and EUC (CBT 12.9% [9/70]; EUC 9.4% [6/64]; $p = 0.52$), and total attrition over the 15 months was 24.6% ($n = 33$) and did not show significant difference between groups ($p = 0.09$). Participants in CBT and EUC differed with regard to baseline PSWQ scores, but this was included as a covariate during analyses.

ITT analyses showed significantly larger improvement of PSWQ in the CBT group compared to EUC (45.6 [95% CI, 43.4–47.8] vs 54.4 [95% CI, 51.4–57.3], $p < 0.001$). A mean change of 7.7 points was measured with CBT group on the PSWQ and 3.2 points in the EUC group. The GADSS did not demonstrate a significant difference between CBT (2.8 points) and EUC (1.4 points). ITT analyses also showed significant improvement on the BDI-II for those completing CBT compared to EUC (10.2 [95% CI, 8.5–11.9] vs 12.8 [95% CI, 10.5–15.1], $p = 0.02$) along with the MCS (CBT 49.6 [95% CI, 47.4–51.8], $p = 0.008$ compared to EUC). Scores on the SIGH-A and PCS were not statistically significant.

No significant increase in medications was noted during the active treatment phase (antianxiety, $p = 0.45$; antidepressant, $p = 0.25$). Similarly, the rates of dose

reduction and discontinuation across the groups were not significant (antianxiety, $p = 0.41$; antidepressant, $p = 0.17$). Both groups had similar number of outpatient medical visits ($p = 0.85$) and infrequent mental health visits ($p = 0.82$). Of those included in the completed analyses, very few participants received a mental health referral (CBT 5/65, EUC 4/50) or spoke to their PCP about emotional issues (CBT 13/65, EUC 9/50).

Continued improvement in PSWQ scores over long-term follow-up was seen in both groups with no significant changes (time effect and group effect) seen with covariate posttreatment analyses indicating no differences between groups, and that treatment response after the active period was maintained. Scores on the MCS and BDI-II were significant on 12-month follow-up indicating that posttreatment effects were maintained. Additionally, rates of medication dose increase, or additions (antianxiety, $p = 0.53$; antidepressant, $p = 0.56$) along with rates of dose reductions or discontinuations (antianxiety, $p = 0.7$; antidepressant, $p = 0.37$) were not different across groups during the long-term follow-up period.

ITT analyses demonstrated a higher treatment response rate at 3 months with the PSWQ. This was not demonstrated with completed analyses at 3 and 15 months. Treatment expectancies were higher in CBT participants compared to those in the EUC group ($p = 0.007$). When added as covariates, the treatment effects were significantly maintained with PSWQ scores ($p < 0.001$). The scores on the BDI-II ($p = 0.05$) and MCS ($p = 0.04$) were close to significance.

Conclusions CBT significantly improved worry severity, depressive symptoms, and general mental health for older adults with GAD in primary care when compared to EUC. Increased GAD severity did not correlate with greater improvement with CBT.

Strengths of the Study

1. The study did careful selection and diagnosis of patients.
2. There was large breadth of outcome assessment.
3. It had excellent treatment integrity using independent rating assessments (GADSS intraclass correlation coefficient = 0.99; SIGH-A intraclass correlation coefficient = 0.95; CBT adherence = 7.7; range 0–8 [SD, 0.55]; CBT competence = 7.3; range 0–8 [SD, 0.67]; EUC calls (20%) reviewed by first author noting only three protocol deviations).
4. There was low attrition in CBT during active treatment phase (0–3 months) [4 dropouts (out of 70 participants) in CBT group compared to 14 dropouts (out of 64 participants) in EUC group; $p = 0.006$].
5. There was significant improvement in PSWQ (score = 45.6, $p < 0.001$), BDI-II (score = 10.2, $p = 0.02$), and MCS (score = 49.6, $p = 0.008$) scale scores in the CBT compared to EUC.
6. Study quality has a Jadad score of 3, which indicates a high quality [2].

Questions Yes (1) No (0)	Was the study described as random?	Was the randomization scheme described and appropriate?	Was the study described as double-blind?	Was the method of double blinding appropriate? (Were both the patient and the assessor appropriately blinded?)	Was there a description of dropouts and withdrawals?	Total score Range of score quality 0–2, low 3–5, high
Score	1	1	0	0	1	3

Limitations of the Study

1. Use of GADSS did not demonstrate treatment effects and may not include appropriate questions to measure late-life GAD.
2. There was limited generalizability due to the participant pool (given age, sex, and education of randomized group).
3. The study had limited reproducibility in a primary care setting due to access to CBT clinicians.
4. The randomized sample was not double-blinded.
5. Communication with the PCP was limited to written notes in a research section of the medical record, and no EMR was available to facilitate treatment integration with ongoing care.

Take-Home Points CBT is beneficial for older adults with GAD in primary care. It can significantly improve worry severity, depressive symptoms, and general mental health for this population.

Practical Applications of the Take-Home Points Primary care centers should consider the integration of CBT into the treatment of GAD in older adults and look into expanding collaborative models of care that incorporate both CBT and medication. Future studies should use an EMR to identify patients and communicate with providers to recruit a more diverse and robust patient population from which more generalizable results may be drawn.

References

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