Coordinated Anxiety Learning and Management (CALM) Tools for Living Program

The Coordinated Anxiety Learning and Management (CALM) Tools for Living Program aims to reduce anxiety and/or depression symptoms and improve the functional status of patients ages 18-75. The program, designed for use in primary care and other outpatient settings, is based on a collaborative care model and cognitive behavioral therapy (CBT); however, the program was developed for use by clinicians with and without CBT expertise.

The 6- to 12-week program brings together the patient, an anxiety clinical specialist (ACS), the patient's primary care provider (e.g., internist, family physician), and a program psychiatrist in the diagnosis and treatment of depression and/or up to four common anxiety disorders: panic disorder, generalized anxiety disorder, social anxiety disorder, and posttraumatic stress disorder. Treatment is flexible, and patients participating in the program can choose to receive one or both of the following components:

- Computer-assisted CBT, which is made up of nine modules: six generic modules (self-monitoring, psychoeducation, fear hierarchy, breathing retraining, relapse prevention, and engagement in physical/positive activities) and three modules (cognitive restructuring, exposure to external stimuli, and exposure to internal stimuli) tailored to the patient's principal disorder (i.e., the most disabling anxiety disorder or depression). The modules are delivered through at least six 60- to 90-minute sessions, during which the ACS and the patient view the computer-assisted CBT program on screen. The program prompts the ACS to engage in specific tasks, such as helping the patient establish a fear hierarchy (e.g., creating a list of sources of anxiety); demonstrating breathing skills, which can be used to help control anxiety; helping the patient practice cognitive skills, which can be used to manage anxiety and conquer fears; conducting interoceptive exposure (e.g., creating the physical sensations of a panic attack); or designing in vivo exposure assignments (e.g., asking the patient to engage in a situation known to induce anxiety). Each patient is given flexibility in the time needed to complete the modules, and a patient can repeat modules or add more sessions to work on reducing symptoms still experienced from the principal disorder or symptoms from a secondary anxiety disorder or depression.
- Pharmacotherapy, through which the patient's anxiety and/or depression symptoms are treated with medication. The program psychiatrist provides the primary care provider with a single-session medication management training, which introduces a medication algorithm. The primary care provider then prescribes medication and remains the clinician of record. The ACS assists the primary care provider by monitoring the patient's medication adherence and providing the patient with behavioral counseling (e.g., to avoid alcohol or caffeine, to optimize sleep hygiene).

Throughout the implementation of the CALM Tools for Living Program, the ACS tracks patient outcomes using a Web-based system that allows for real-time monitoring of recruitment, enrollment, diagnoses, ineligibility, patient contact information, and continuous and session-specific symptom assessments of patients. The ACS also interacts regularly with primary care providers in person and by phone. The program psychiatrist also provides consultation to primary care providers by phone, and patients with complex cases or those not responding to treatment can be seen by the program psychiatrist.

ACSs are usually case managers, social workers, registered nurses, or master's- or doctoral-level psychologists with patient care experience in primary care or psychiatric settings. However, familiarity with CBT is not a requirement, and ACSs receive training on the computer-assisted CBT program and the use of medications in treating anxiety. In addition, throughout the program, ACSs receive phone-based group supervision on a weekly basis from an expert psychologist and psychiatrist for diagnostic, CBT, and medication management issues.

Descriptive Information

Areas of Interest	Mental health treatment
Outcomes	**Review Date: July 2012** 1: General symptoms of anxiety 2: Disorder-specific symptoms of anxiety 3: Symptoms of depression 4: Functional status
Outcome Categories	Mental health Quality of life Social functioning

Ages	18-25 (Young adult) 26-55 (Adult) 55+ (Older adult)
Genders	Male Female
Races/Ethnicities	Black or African American Hispanic or Latino White Race/ethnicity unspecified
Settings	Outpatient
Geographic Locations	Urban Suburban
Implementation History	The CALM Tools for Living Program was first implemented and evaluated in 2006 at 17 primary care clinics with 1,004 participants in Arkansas, California, and Washington. The program is being implemented at the Mayo Clinic in Minnesota, and so far, 70 clients have received the treatment through a primary care clinic.
NIH Funding/CER Studies	Partially/fully funded by National Institutes of Health: Yes Evaluated in comparative effectiveness research studies: Yes
Adaptations	The program materials have been translated into Spanish, and the original validation sample included both English and Spanish speakers.
Adverse Effects	No adverse effects, concerns, or unintended consequences were identified by the developer.
IOM Prevention Categories	IOM prevention categories are not applicable.

Quality of Research
Review Date: July 2012

Documents Reviewed

The documents below were reviewed for Quality of Research. The research point of contact can provide information regarding the studies reviewed and the availability of additional materials, including those from more recent studies that may have been conducted.

Study 1

Craske, M. G., Stein, M. B., Sullivan, G., Sherbourne, C., Bystritsky, A., Rose, R. D., et al. (2011). Disorder-specific impact of Coordinated Anxiety Learning and Management treatment for anxiety disorders in primary care. Archives of General Psychiatry, 68(4), 378-388. PubMed

Roy-Byrne, P., Craske, M. G., Sullivan, G., Rose, R. D., Edlund, M. J., Lang, A. J., et al. (2010). Delivery of evidenced-based treatment for multiple anxiety disorders in primary care. A randomized controlled trial [Including data supplement: eTable 1. Adjusted means for anxiety outcomes]. Journal of the American Medical Association, 303(19), 1921-1928. PubMed

Supplementary Materials

Craske, M. G., Rose, R. D., Lang, A., Welch, S. S., Campbell-Sills, L., Sullivan, G., et al. (2009). Computer-assisted delivery of cognitive behavioral therapy for anxiety disorders in primary-care settings. Depression and Anxiety, 26(3), 235-242. PubMed

Outcomes

Outcome 1: General symptoms of anxiety	
Description of Measures	General symptoms of anxiety were assessed using the 12-item Brief Symptom Inventory (BSI-12), a generic measure of two key components of all anxiety disorders (i.e., psychic and somatic anxiety). Using a scale ranging from 0 (not at all) to 4 (extremely), participants rate how distressed they were by each symptom (e.g., "faintness or dizziness," "feeling tense or keyed up," "spells of terror or panic") over the past 7 days. Scores for each item are summed, and total scores range from 0 to 48; higher scores indicate more anxiety symptoms with greater severity.

In addition, participants' achievement of response to treatment (i.e., response rate) was calculated as the percentage of participants who had at least a 50% reduction in the BSI-12 total score from baseline to a follow-up assessment, and participants' achievement of remission (i.e., remission rate) was calculated as the percentage of participants who had a BSI-12 total score of less than 6 at a follow-up assessment.

Key Findings	A study was conducted in 17 primary care clinics with 18- to 75-year-old patients with anxiety disorders (with or without major depression). Participants were randomly assigned to receive either the CALM Tools for Living Program or usual care (i.e., continued treatment by their physician with medication, counseling, or referral to a mental health specialist). The CALM Tools for Living Program was delivered over 10-12 weeks, and if necessary, participants received the program for another 10-12 weeks. After completing the program, participants received monthly phone calls to reinforce CBT skills and medication adherence for up to a year from the beginning of the study. Data were collected at baseline and at 6, 12, and 18 months after baseline (follow-up assessments). Results of the initial BSI-12 assessment indicated that there was no statistically significant difference between the intervention and usual care groups at baseline. Findings included the following: • Compared with participants who received usual care, those who received the intervention had lower BSI-12 total scores at the 6-month ($p < .001$), 12-month ($p < .001$), and 18-month ($p = .05$) follow-up assessments. These results were associated with effect sizes that were small (Cohen's $d = 0.30$ and 0.31 at the 6- and 12-month follow-up assessments, respectively) and very small (Cohen's $d = 0.18$ at the 18-month follow-up assessment). • Compared with participants who received usual care, those who received the intervention had higher response rates at the 6-month ($p < .001$), 12-month ($p < .001$), and 18-month ($p < .001$) follow-up assessments. • Compared with participants who received usual care, those who received the intervention had higher remission rates at the 6-month ($p < .001$), 12-month ($p < .001$), and 18-month ($p < .001$) follow-up assessments.
Studies Measuring Outcome	Study 1
Study Designs	Experimental
Quality of Research Rating	3.6 (0.0-4.0 scale)

Outcome 2: Disorder-specific symptoms of anxiety

Description of Measures	Disorder-specific symptoms of anxiety were assessed using three measures: • Panic Disorder Severity Scale--Self Report (PDSS-SR). The PDSS-SR is a 7-item measure designed to assess panic disorder. Using a scale ranging from 0 to 4, with varying answers for each anchor, participants rate their experience regarding panic disorder over the past week. A sample item is, "During the past week, how much have you worried or felt anxious about when your next panic attack would occur, or about fears related to the attacks (for example, that they could mean you have physical or mental health problems or could cause you social embarrassment)?" Responses to this item range from 0 (not at all) to 4 (nearly constantly and to a disabling extent). Scores for each item are summed, and total scores range from 0 to 28; higher scores indicate more panic disorder symptoms with greater severity. • Generalized Anxiety Disorder Severity Scale (GADSS). The GADSS is a 6-item measure of generalized anxiety disorder symptoms. Using a scale ranging from 0 (not at all) to 4 (extremely), participants rate their experience regarding each item (e.g., "Over the past week, how often did you experience these symptoms? Did you have these symptoms every day?" and "On average, during how much of each day did you have one or more of these symptoms?"). Scores for each item are summed, and total scores range from 0 to 24; higher scores indicate more generalized anxiety disorder symptoms with greater severity. • Social Phobia Inventory (SPIN). The SPIN is a 17-item measure of social phobia symptoms of social anxiety disorder. Using a scale ranging from 0 (not at all) to 4 (extremely), participants rate their experience regarding each symptom described in an item (e.g., "I am afraid of people in authority," "I avoid talking to people I don't know"). Scores for each item are summed, and total scores range from 0 to 68; higher scores indicate more social phobia symptoms with greater severity. In addition, participants' achievement of response to treatment (i.e., response rate) was calculated as the percentage of participants who had at least a 40% reduction in each measure's total score from baseline to a follow-up assessment, and participants' achievement of remission (i.e., remission rate) was calculated as the percentage of participants who had a PDSS-SR total score of less than or equal to 7, a GADSS total score of less than or equal to 6, or a SPIN total score of less than or

	equal to 18 at a follow-up assessment.
Key Findings	A study was conducted in 17 primary care clinics with 18- to 75-year-old patients with anxiety disorders (with or without major depression). Participants were randomly assigned to receive either the CALM Tools for Living Program or usual care (i.e., continued treatment by their physician with medication, counseling, or referral to a mental health specialist). The CALM Tools for Living Program was delivered over 10-12 weeks, and if necessary, participants received the program for another 10-12 weeks. After completing the program, participants received monthly phone calls to reinforce CBT skills and medication adherence for up to a year from the beginning of the study. Data were collected at baseline and at 6, 12, and 18 months after baseline (follow-up assessments). Results of the initial PDSS-SR, GADSS, and SPIN assessments indicated that there were no statistically significant differences between the intervention and usual care groups at baseline. Findings included the following:

- Compared with participants who received usual care, those who received the intervention had lower PDSS-SR total scores at the 6-month ($p = .036$) and 12-month ($p = .003$) follow-up assessments. These results were associated with small effect sizes (Cohen's d = 0.35 and 0.46 at the 6- and 12-month follow-up assessments, respectively). There was no statistically significant difference in PDSS-SR total scores between groups at the 18-month follow-up assessment; response rates also did not differ significantly between groups at any of the follow-up assessments. However, compared with participants who received usual care, those who received the intervention had a higher remission rate at the 12-month ($p < .03$) follow-up assessment; findings were not significant at the 6- and 18-month follow-up assessments.
- Compared with participants who received usual care, those who received the intervention had lower GADSS total scores at the 6-month ($p < .001$), 12-month ($p < .001$), and 18-month ($p < .001$) follow-up assessments. These results were associated with effect sizes that were small (Cohen's d = 0.33 at the 6-month follow-up assessment) and medium (Cohen's d = 0.51 and 0.64 at the 12- and 18-month follow-up assessments, respectively). In addition, compared with participants who received usual care, those who received the intervention had higher response rates at the 6-month ($p < .001$), 12-month ($p < .001$), and 18-month ($p < .001$) follow-up assessments and higher remission rates at the 6-month ($p < .01$), 12-month ($p < .001$), and 18-month ($p < .001$) follow-up assessments.
- Compared with participants who received usual care, those who received the intervention had a lower SPIN total score at the 6-month follow-up assessment ($p = .026$). This result was associated with a medium effect size (Cohen's d = 0.53). In addition, compared with participants who received usual care, those who received the intervention had a higher response rate at the 6-month ($p < .04$) follow-up assessment. There were no statistically significant differences in SPIN total scores or in response rates between groups at the 12- and 18-month follow-up assessments; the remission rates also did not differ significantly between groups at any of the follow-up assessments. |
Studies Measuring Outcome	Study 1
Study Designs	Experimental
Quality of Research Rating	3.7 (0.0-4.0 scale)

Outcome 3: Symptoms of depression	
Description of Measures	Symptoms of depression were assessed using the Patient Health Questionnaire 8 (PHQ-8), an 8-item measure of depression severity. Using a scale ranging from 0 (not at all) to 3 (nearly every day), participants rate their experience regarding each symptom (e.g., "little interest or pleasure in doing things," "feeling down, depressed, or hopeless," "feeling tired or having little energy") over the past 2 weeks. Scores for each item are summed, and total scores range from 0 to 24; higher scores indicate more symptoms of depression with greater severity.
Key Findings	A study was conducted in 17 primary care clinics with 18- to 75-year-old patients with anxiety disorders (with or without major depression). Participants were randomly assigned to receive either the CALM Tools for Living Program or usual care (i.e., continued treatment by their physician with medication, counseling, or referral to a mental health specialist). The CALM Tools for Living Program was delivered over 10-12 weeks, and if necessary, participants received the program for another 10-12 weeks. After completing the program, participants received monthly phone calls to reinforce CBT skills and medication adherence for up to a year from the beginning of the study. Data were collected at baseline and at 6, 12, and 18 months after baseline (follow-up assessments). Results of the initial PHQ-8 assessment indicated that there was no statistically significant difference between the intervention and usual care groups at baseline. Compared with participants who received usual

care, those who received the intervention had lower PHQ-8 total scores at the 6-month (p = .002), 12-month (p < .001), and 18-month (p = .006) follow-up assessments. These results were associated with small effect sizes (Cohen's d = 0.25, 0.37, and 0.24 at the 6-, 12-, and 18-month follow-up assessments, respectively).

Studies Measuring Outcome	Study 1
Study Designs	Experimental
Quality of Research Rating	3.7 (0.0-4.0 scale)

Outcome 4: Functional status

Description of Measures	Functional status was assessed using the following measures: • 12-item Short Form Health Survey version 2 (SF-12v2), a measure of physical and mental health. Using a scale ranging from 1 to 5, participants rate each item (e.g., "During the past 4 weeks, how much of the time have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?" and "During the past 4 weeks, how much did pain interfere with your normal work, including both work outside the home and housework?"). Scores for each item are summed to produce physical health and mental health composite scores, and higher scores indicate better functional status. • Centers for Disease Control and Prevention "Healthy Days Measure," a 1-item measure of physical and mental health: "During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?" Participants respond by providing the number of days. • Sheehan Disability Survey (SDS), a 3-item measure of functional impairment. Using a scale ranging from 0 (not at all) to 10 (extremely), participants rate how disrupted their functioning has been across three different contexts: "The symptoms have disrupted your work/school work," "The symptoms have disrupted your social life/leisure activities," and "The symptoms have disrupted your family life/home responsibilities." Scores for each item are summed, and total scores range from 0 to 30; higher scores indicate a higher level of functional impairment.
Key Findings	A study was conducted in 17 primary care clinics with 18- to 75-year-old patients with anxiety disorders (with or without major depression). Participants were randomly assigned to receive either the CALM Tools for Living Program or usual care (i.e., continued treatment by their physician with medication, counseling, or referral to a mental health specialist). The CALM Tools for Living Program was delivered over 10-12 weeks, and if necessary, participants received the program for another 10-12 weeks. After completing the program, participants received monthly phone calls to reinforce CBT skills and medication adherence for up to a year from the beginning of the study. Data were collected at baseline and at 6, 12, and 18 months after baseline (follow-up assessments). Results of the initial SF-12v2, Healthy Days Measure, and SDS assessments indicated that there were no statistically significant differences between the intervention and usual care groups at baseline. Findings included the following: • Compared with participants who received usual care, those who received the intervention had an increase in SF-12v2 mental health composite scores at the 6-month (p < .001), 12-month (p < .001), and 18-month (p < .001) follow-up assessments. These results were associated with small effect sizes (Cohen's d = 0.34, 0.47, and 0.39 at the 6-, 12-, and 18-month follow-up assessments, respectively). There were no statistically significant differences in the SF-12v2 physical health composite scores between groups at any of the follow-up assessments. • Compared with participants who received usual care, those who received the intervention reported fewer days of poor health that kept them from usual activities (Healthy Days Measure) at the 6-month (p = .005), 12-month (p = .05), and 18-month (p = .02) follow-up assessments. These results were associated with effect sizes that were small (Cohen's d = 0.24 and 0.21 at the 6- and 12-month follow-up assessments, respectively) and very small (Cohen's d = 0.19 at the 18-month follow-up assessment). • Compared with participants who received usual care, those who received the intervention had lower SDS total scores at the 6-month (p < .001), 12-month (p < .001), and 18-month (p < .001) follow-up assessments. These results were associated with small effect sizes (Cohen's d = 0.32, 0.44, and 0.35 at the 6-, 12-, and 18-month follow-up assessments, respectively).
Studies Measuring Outcome	Study 1
Study Designs	Experimental

Quality of Research Rating	3.7 (0.0-4.0 scale)

Study Populations

The following populations were identified in the studies reviewed for Quality of Research.

Study	Age	Gender	Race/Ethnicity
Study 1	18-25 (Young adult) 26-55 (Adult) 55+ (Older adult)	71.1% Female 28.9% Male	56.6% White 19.5% Hispanic or Latino 12.4% Race/ethnicity unspecified 11.6% Black or African American

Quality of Research Ratings by Criteria (0.0-4.0 scale)

External reviewers independently evaluate the Quality of Research for an intervention's reported results using six criteria:

1. Reliability of measures
2. Validity of measures
3. Intervention fidelity
4. Missing data and attrition
5. Potential confounding variables
6. Appropriateness of analysis

For more information about these criteria and the meaning of the ratings, see Quality of Research.

Outcome	Reliability of Measures	Validity of Measures	Fidelity	Missing Data/Attrition	Confounding Variables	Data Analysis	Overall Rating
1: General symptoms of anxiety	3.8	3.8	3.5	3.8	3.0	4.0	**3.6**
2: Disorder-specific symptoms of anxiety	3.8	3.9	3.5	3.8	3.0	4.0	**3.7**
3: Symptoms of depression	3.8	4.0	3.5	3.8	3.0	4.0	**3.7**
4: Functional status	4.0	4.0	3.5	3.8	3.0	4.0	**3.7**

Study Strengths

The measures have acceptable, documented levels of reliability and validity. Treatment fidelity was maximized through multiple efforts, including training of the ACSs in CBT and medication management, ongoing supervision of the ACSs, real-time Web-based outcomes monitoring that optimized treatment decisions, and a computer-assisted program to optimize delivery of CBT by nonexpert care managers (i.e., ACSs) who also assisted primary care providers in promoting patients' adherence to medications, optimizing their use of medications, and providing patients with behavioral counseling. Attrition was relatively low, with 80% of participants completing the 18-month follow-up assessment, and researchers provided information on the number of participants who dropped out at each step of the study, as well as reasons for attrition. The study used a randomized design. Data analyses were appropriate and used an intent-to-treat design.

Study Weaknesses

As noted by the researchers, the intervention is made up of a blended package of treatment components; thus, it is not possible to disentangle which specific treatment component or combination of components accounted for the results.

Readiness for Dissemination
Review Date: July 2012

Materials Reviewed

The materials below were reviewed for Readiness for Dissemination. The implementation point of contact can provide information regarding implementation of the intervention and the availability of additional, updated, or new materials.

CALM Tools for Living modules

CALM Tools for Living training handouts:

- Handout 1: Packet From Workbook
- Handout 2: Disorder Illustrations
- Handout 3: Role Play Scenarios
- Handout 4: Medication Matrix

CALM Tools for Living Training Workbook

CALM Tools for Living videos

Program Web site, http://www.calmtoolsforliving.org/

Readiness for Dissemination Ratings by Criteria (0.0-4.0 scale)

External reviewers independently evaluate the intervention's Readiness for Dissemination using three criteria:

1. Availability of implementation materials
2. Availability of training and support resources
3. Availability of quality assurance procedures

For more information about these criteria and the meaning of the ratings, see Readiness for Dissemination.

Implementation Materials	Training and Support Resources	Quality Assurance Procedures	Overall Rating
4.0	3.5	3.3	**3.6**

Dissemination Strengths

The electronic program materials are thorough and user-friendly. Each program module includes readings for the patient, prompts for discussions between the patient and his or her treatment provider, and exercises for use by the patient between treatment sessions. The intervention process is clearly explained to the patient and treatment provider, and videos describing this process are included in the implementation materials. The training workbook includes useful and practical exercises, clearly describes anxiety disorders, and is nicely designed and formatted for ease of use. The materials include coaching approaches and techniques for use by treatment providers when patients are unsure of their progress in treatment or want to discontinue treatment. The quality assurance materials are strength based, provide treatment providers with concrete guidance regarding patient progress, and provide good feedback loops.

Dissemination Weaknesses

The program Web site provides limited information on the cost of the required training and the availability of technical or follow-up support. Although some information incorporated into the computer program can be used for quality assurance purposes, there are no comprehensive protocols available for objectively assessing adherence to the model or progress toward improvement of participant outcomes.

Costs

The cost information below was provided by the developer. Although this cost information may have been updated by the developer since the time of review, it may not reflect the current costs or availability of items (including newly developed or discontinued items). The implementation point of contact can provide current information and discuss implementation requirements.

Item Description	Cost	Required by Developer
CALM Tools for Living Training Workbook and handouts	Included in the cost of the training	Yes
License for CALM Tools for Living computer program	- For 1-20 clinicians, $495 per clinician per year - For 21-40 clinicians, $9,500 per year - For more than 40 clinicians, varies depending on the scope of use	Yes
2-day, off-site training in Seattle, WA	$395-$495 per person (depending on venue) for up to 50 participants	Yes
Tailored on-site organizational training	Varies depending on the scope of services	No

Email-based technical support for computer program	Included in the cost of the license	No
Monthly implementation consultation calls	$7,000 per year	No

Replications

No replications were identified by the developer.

Contact Information

To learn more about implementation or research, contact:

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Consider these Questions to Ask (PDF, 54KB) as you explore the possible use of this intervention.

Web Site(s):

- **http://www.calmtoolsforliving.org/**

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