The EXTENDED RELIEF Study: Cognitive-Behavioral Therapy Plus Escitalopram in the Management of Late-life Anxiety

Therapist Manual

Manual adapted from White, 1999; Zinbarg, Craske, & Barlow, 1993; and
CALM Study Workbook by Julie Loebach Wetherell, Ph.D., Jill A. Stoddard, Ph.D.,
Laura Otis, Ph.D., and John T. Sorrell, Ph.D.
University of California, San Diego and VA San Diego Healthcare System

Eric J. Lenze, M.D., and Sander Kornblith, Ph.D.
Western Psychiatric Institute and Clinics, University of Pittsburgh

The EXTENDED RELIEF Study
Table of Contents

Introduction

Anxiety in Older Adults

Anxiety is common in older adults, with an estimated 6%-10% meeting criteria for an anxiety disorder. The most common anxiety disorder in late life is generalized anxiety disorder (GAD). The EXTENDED RELIEF Study is intended for patients over the age of 60 with GAD. Participants in this study will receive a sequence of escitalopram treatment followed by Cognitive-Behavioral Therapy to examine maintenance effects.

The EXTENDED RELIEF Study Intervention

The CBT portion of the EXTENDED RELIEF program is the second phase of treatment in the study. At this point, participants have been taking escitalopram daily (10-20mg) for 12 weeks and have achieved partial or full response. In this second phase, the goal of treatment is to teach participants skills to further decrease their anxiety and worry if necessary and to help them manage their anxiety in the future, with or without medication. All patients will continue to receive escitalopram during this phase. Following 16 weeks of escitalopram plus CBT, half the patients will be tapered to placebo in a double-blind format for a 52-week maintenance phase. Thus, the main objective of the study is to see whether CBT provides protection against relapse when medication is withdrawn.

The EXTENDED RELIEF Study intervention consists of 16 weekly sessions of individual CBT comprised of a variety of topics and skills intended to address the problems and symptoms most commonly encountered among anxious older adults. There are 12 sessions of required content in this protocol. The remaining 4 sessions can be used for optional modules, open sessions, or additional

skills practice. The Project Coordinator will let therapists know whether each patient qualifies for any of the optional modules. Module contents are as follows:

- *Recognizing Worry and Anxiety (2 sessions):* Psychoeducation about anxiety, monitoring of physical, cognitive, and behavioral symptoms, and finding out about the patient's history of stressful events and coping style.

- *Optional: Anxiety and the Family (1 session): If a close family member (spouse, adult child) is available and supportive.* Provide the family member with information about anxiety and treatment, solicit support for the patient during treatment, and gather collateral information about the patient's anxiety symptoms and functioning.

- *Learning to Relax (3 sessions):* Diaphragmatic breathing, progressive muscle relaxation, and guided imagery.

- *Positive Action (3 sessions):* Problem solving skills training: identifying a specific problem, brainstorming solutions, evaluating advantages and disadvantages, and implementing the best solution.

- *Changing Your Thinking (3 sessions):* Identifying and challenging automatic negative thoughts and maladaptive schema.

- *Optional: Increasing Pleasure (2 sessions): If patient scored 3 or greater for two consecutive weeks on the Hamilton Mood item during the 12 weeks of open-label escitalopram or experienced a major depressive episode within the year prior to enrollment.* Behavioral activation for depression or depressive symptoms.

- *Optional: Facing Your Fears (2 sessions): If patient scored 3 or greater for two consecutive weeks on the Hamilton Fears item during the 12 weeks of open-label escitalopram or experienced an anxiety disorder within the year prior to enrollment.* Exposure therapy for phobias, panic, agoraphobia, and PTSD.

- *Optional: Getting to Sleep (1 session): If patient scored 3 or greater for two consecutive weeks on the Hamilton Insomnia item during the 12 weeks of open-label escitalopram.* Sleep hygiene.

- *Maintaining Your Progress (1 session):* Review concepts and techniques learned over the course of treatment, identify "early warning signs" and

create a plan should the patient notice a recurrence of anxiety, and talk about termination of therapy.

Open sessions: Clinical experience has taught us that patients sometimes encounter issues during the course of treatment that may not be addressed within the context of a structured manualized protocol. Therefore, as many as 2 sessions could be used as "open" sessions, without a predetermined agenda. There is no section of the therapist or patient workbook specifically for open sessions. Their content is determined by the therapist based on the individual needs of the patient as they arise. Examples include crisis intervention (e.g., a family member being hospitalized) or addressing therapy-interfering behaviors (e.g., inconsistent attendance, lack of homework compliance).

Even though an open session may not correspond to the content of a specific session, it is advisable to continue to assign at-home practice, using whatever practice sheets seem most appropriate. For example, suppose that a patient was supposed to start the Changing Your Thinking module, but instead came in reporting that a family member had become severely ill. The session may involve supportive counseling and crisis management rather than cognitive therapy. The therapist might suggest that the patient engage in relaxation as a form of self-care during the crisis and therefore might provide at-home practice sheets from the Relaxation module. Following a session devoted to discussion of therapy-interfering behavior, the therapist might assign at-home practice forms from the Recognizing Anxiety module in order to encourage the patient to monitor anxiety.

If a patient does not meet criteria for the optional sessions and has no crises or other issues requiring an open session, he/she will have 3 sessions (4 if no family member is available for a family session) to practice skills. Therapists should work on whatever would be most helpful for that patient, using the appropriate practice sheets. For example, a patient who is working on behavioral change would be encouraged to continue making progress in this area, using the Positive Action practice sheets to facilitate this process.

It is possible that some patients will be eligible for more than 4 sessions worth of optional modules (e.g., family plus exposure plus behavioral activation), or a major crisis (e.g., homelessness) could interfere with covering the required material. If this is the case, discuss the situation with the therapist supervisory team and decide which modules should be prioritized. In general, it is better to omit something entirely than to try to cover too many things in insufficient depth.

Booster Sessions: As many as six booster sessions may be conducted at any time during the 52-week maintenance phase should a patient's symptoms start to recur. Patients should be informed that they may contact the therapist at any time

during the remainder of their participation in the study should they feel a return of symptoms and wish to review and practice skills. Alternatively, therapists may contact patients should structured study assessments reveal that patients are deteriorating. Booster sessions may be in person or over the telephone. These sessions are intended to constitute a review of skills previously learned in treatment and to apply those skills to increases in anxiety that may accompany medication discontinuation or occur in response to an unanticipated life stressor. We recommend that you collaborate with the patient to decide which specific skills would be most helpful to discuss and practice during booster sessions. At-home practice forms should be used consistent with whatever skills are being reviewed.

It is not required that all six sessions be used, and in our experience, a "bolus" of three sessions over a period of 4 weeks (with a two week gap between sessions 2 and 3) is usually sufficient to reengage the patient in skills practice and reduce anxiety symptoms. Especially if a patient is relapsing during the first 6 months of maintenance, it is recommended that the therapist use no more than 3 sessions to save the last 3 sessions for possible future symptomatic exacerbations.

It is important that you try to see your patient for his/her CBT session every week, as all 16 sessions must be completed by the end of week 16 to correspond with the 16 weeks of medication prior to taper. If a patient cannot attend his/her scheduled session, attempt to fit them in some other time that week. Avoid doubling up sessions during the final weeks of treatment.

Research has shown that older adults have higher rates of inconsistent attendance and treatment drop-out. Therefore, in an effort to maximize participation, you may elect to conduct up to four treatment sessions over the telephone (though it is not required). This is particularly helpful in weeks when you need to schedule two sessions to make up for a missed session. Do not introduce a brand new topic during a phone session. This may mean, for example, that you would spend a fourth session on Relaxation rather than moving on to Positive Action.

Cognitive-Behavioral Therapy (CBT) Model

Optimally, therapists using this protocol will have substantial experience using Cognitive Behavioral Therapy, although not necessarily with older adults with anxiety disorders. Some of the material that follows will be obvious to a CBT practitioner. However, there are some issues that are specific to anxious older adults, as well as to the EXTENDED RELIEF protocol. **The best way to familiarize yourself with this protocol is to first read the therapist and patient manuals, then watch videos of therapists working with patients.** As when

starting any new therapy protocol, expect to feel a little nervous, at least for the first few sessions.

CBT is focused on evaluating relationships between thoughts, feelings, and behaviors, as well as implementing strategies to lessen symptoms and reduce avoidant behavior. COGNITIVE refers to the power of our beliefs. Beliefs about ourselves, our world, and our future have a strong influence on what actually happens. CBT brings these kinds of beliefs into direct awareness so that we can determine which beliefs are strong and valuable that we want to sustain, and which beliefs may have some kind of basis in the past and have outlived their usefulness.

BEHAVIOR acknowledges that real change happens in our life only when we do things differently. There needs to be some kind of action that brings new direction to life. CBT focuses on assisting patients to translate what they learn during sessions into their day-to-day life. For this reason, at-home practice exercises are used in the EXTENDED RELIEF Study intervention. At-home assignments give participants more opportunity to practice what they learn in therapy and apply it to their daily experience. The central role of homework is one of the reasons attributed to why CBT is among the best methods in therapeutic improvement. A recent pooled analysis of three psychotherapy trials for older adults with GAD found that the amount of at-home practice was the most consistent predictor of symptom reduction, which justifies the focus on homework assignments in the EXTENDED RELIEF Study intervention.

The collaborative relationship between the therapist and patient is central to CBT. This means that you and your EXTENDED RELIEF Study participant will be working as partners to get the best possible results. You will be a coach to your EXTENDED RELIEF Study participant as you provide 16-22 sessions of individual therapy (including booster sessions if needed). In regards to the at-home practice exercises, you will maintain a therapeutic relationship with your patient that is supportive of real change while being respectful of individual responsibility and choice about completing the homework assignments and applying new skills in daily life.

Therapist Style

Try to use a "Socratic" questioning style with your patients. For example, you can use a series of questions to teach about the three-component model of anxiety:

- "Think about times you've felt anxious in the past week. What were you doing? Where were you? What happened right before you started feeling anxious? What physical sensations did you notice? What went through your

mind? What did you do as a result of your anxiety? Can you think of ways that these thoughts, feelings, and actions worked together to make you feel worried or anxious?"

Motivational interviewing techniques are also helpful:

- Questions to ask are those that explore ambivalence, such as "what are the benefits of doing these at-home exercises, and what are the disadvantages?"

- Statements that develop a sense of discrepancy between what the patient is currently experiencing and what they would like to experience instead are also helpful: "So you say you need to stay up late at night doing paperwork. Yet you also say you are getting up too late to make use of your mornings and you'd like to feel less anxious and stressed when you can't get all your phone calls, errands, etc. done during the afternoons. What do you think about that?"

- Give patients a sense that they are responsible for change, and also capable of making change. "Only you can make that happen. No one can do it for you. But you were able to make a change in XX situation, so you have the ability to do it now, if you choose to. The question is whether you're willing to do it."

- Push the patient to explore alternatives. Use the daily anxiety scale on the homework form (or the weekly PSWQ) to help you. "So you've been averaging about a 6 on daily anxiety. What would have to change to have that go down 1 point? What would you be willing to do to make that happen?"

Be aware of doing too much work for the patient. For example, it is better to have the patient, rather than the therapist, write when writing is called for in session. Also, try to get the patient to come up with examples or articulate rationales for particular exercises, rather than supplying them all yourself.

Often patients will speak in general terms about a situation, which can make it hard to tease apart specific thoughts, feelings, and behaviors. It is often helpful to have the patient close his or her eyes and imagine that the situation is happening right now. Sometimes this involves remembering the last time the situation came up, and sometimes it involves imagining a situation. Either way, once the patient is in the situation in his or her imagination, ask the patient what he or she is thinking, feeling in his or her body, what s/he has an impulse to do, etc.

Because of anxiety, patients often avoid dealing with their most problematic situations, leading to the "elephant in the room" phenomenon (e.g., patient wants to work on cleaning the garage for Positive Action and not address the fact that a drug-abusing adult child is living rent-free in the home). Because the focus of this study is on keeping a patient well in the long term, it is more helpful to work on major problems, which are likely to resurface and cause problems over time, than minor ones. You may need to have a discussion about the advantages and disadvantages of this with a patient, along with your recommendation that he/she take advantage of time in therapy to tackle the harder things now, rather than risk them becoming a crisis later on. You can assure a patient that it is not your role to insist on any particular course of action, but rather to give the patient a safe environment and new skills to think about problems and potential problems that lead to worry and anxiety.

When introducing new material, it is often helpful for the therapist to guide the patient using an example the therapist has noticed from the patient's own life. For example, when talking about triggers for anxiety, the therapist could start by stating a situation the patient has worried about, e.g., "You said last week that you often feel anxious when talking to your daughter. Let's practice what you can do to help you the next time you're with your daughter and you start feeling anxious." This is particularly important for the Changing Your Thinking module because it is difficult for many patients to identify negative thoughts.

It is helpful to ask questions frequently, including as new material is introduced, to determine the patient's level of understanding of the purpose of skills and practice exercises, such as, "Why do you think we are doing this? How might this help with your worry?" Also, end each session by asking your patient to summarize what they have learned. For homework, they should read the Patient Workbook and jot down the most important points in the space provided.

Patients often do not call their problem anxiety or worry. Let the patient choose a term they endorse during the first session, and remember to use that term throughout the therapy. "Stress" works for many people. Tell the patient he or she can cross out the words they don't identify with and write in a different word in the workbook or at-home practice sheets if they like.

Some patients have a tendency to digress. One strategy is to break the flow to summarize frequently and then redirect the conversation. Another strategy is to tell the patient up front that in order to make the best use of their time and cover the material, you may need to interrupt the patient to move on, and ask their permission in advance to do so. It is important to talk about what patients are currently dealing with in their lives in order to brainstorm ways in which the skills taught in the protocol can be helpful. Talking extensively about the past, or about

world events or problems affecting people close to the patient, is not usually helpful and can be redirected by asking, "how is this affecting you personally, right now?"

General Session Guidelines

Methods to enhance learning by older adults were taken into consideration in developing the EXTENDED RELIEF Study workbook for participants. Research has shown that older adults have more difficulty with memory than younger adults. Therefore, material is repeated and reviewed frequently. Because of age-associated declines in abstract reasoning ability, certain cognitive therapy techniques like formal cognitive restructuring (e.g., "What's the evidence for this? What's the evidence against?") are downplayed in this program. However, we do teach participants to identify negative thoughts and generate alternative thoughts or behaviors as coping strategies when they observe those negative thoughts. Also, patients may have trouble generalizing from an abstract example. Consistent with "Socratic," open-ended questioning, you should only use examples from your patient's life to teach important concepts. In general, always be on alert for examples from the patient to use later during the course of therapy. You should generally work through at least two examples from your patient's life to demonstrate a new coping skill.

The typical structure of a session is to start by setting an agenda, give and score the brief PSWQ, ask about any medication issues, review at-home practice, introduce the rationale for a new skill, teach the skill, and assign at-home practice. Since most skills are covered in multiple sessions, the last session in each module should not cover any new material and should focus on integrating the skill into the patient's daily life. At the very end of each session, ask the participant to summarize what was covered to consolidate learning.

Workbook and Forms

Don't give participants the entire EXTENDED RELIEF Study workbook at once. Instead, give participants a copy of the chapter you'll be covering each session in which you present new material. Encourage participants to read the material at home, which will summarize and supplement what is discussed in session. You should focus your sessions on teaching important concepts and skills through the use of real-life examples rather than reviewing all of the didactic material provided in the EXTENDED RELIEF Study workbook. Instruct your patient to bring this manual with them to every session. If a patient does not bring their manual to two consecutive sessions, bring a second copy of all the materials with you. You can give them this copy and remind them to bring it to every

session. This sends a clear message regarding the importance of bringing the manual and the practice assignments.

Don't feel pressured to cover everything in the Patient Workbook. For example, in the first session, as is indicated in the Session 1 outline in the Therapist Manual below, you don't need to discuss the facts about worry and anxiety or the definition of GAD. In general, the material in the workbook is intended as either a supplement to or reminder of what was discussed in session. **The most important part of every session is learning the skills: helping the patient understand the rationale, teaching the skill in session, and encouraging at-home practice.**

Using the workbook in session requires a balance between completing some exercises in session and referring the patient to material to be read at home. Except when the manual includes a script (e.g., for relaxation training) or some material for the patient to write in session (e.g., situations, physical sensations, thoughts, and behaviors associated with anxiety), try not to read directly from the manual. However, it is appropriate to point out important information in the Patient Workbook to encourage the patient to read and think about it between sessions (e.g., the three components of anxiety).

At several points, you may want to use index cards for patients to write down important reminders, such as coping thoughts or skills. Patients should be encouraged to carry these with them to cue them to engage in more adaptive coping.

At the beginning of every session except the family session, you will administer the Penn State Worry Questionnaire in order to track the patient's progress. Sum the items in session. It may be helpful to show the patient the pattern of progress over time. Some patients may consistently report all 1's or all 5's. It is helpful in the early stage of treatment to teach patients why and how to recognize fluctuations in their anxiety. More information about the rationale for monitoring appears below, in the Recognizing Your Anxiety and Worry chapter.

You should also check in with patients very briefly about their medication use. In our experience, most patients will report that they had no problems or concerns about the medication. For those who do have concerns, listen and try to clarify the issues, then let them know that a study physician will contact them. Give the physician the information as soon as possible. In our experience with anxious older adults, it is best if patients are called within 24 hours, even if the issue seems relatively minor.

Dealing with medication issues is an important aspect of CBT in the EXTENDED RELIEF program. Achieving some level of improvement with

escitalopram is required in order for the patient to remain in the study. As a result of successful or partially successful medication treatment, however, participants may develop the belief that they are not able to cope with worry or anxiety without medication. The goal of this program is to help participants learn that medication is one useful tool for managing anxiety, but coping strategies, including those taught in this program, can also help with worry and anxiety. Ideally, therapy should help participants learn that anxiety is not catastrophic, and that they are able to use techniques to help manage it. It is therefore important to check in about and listen for red flags such as worrying about re-experiencing symptoms that they had before starting the medication, expressing concern about whether or when the medication will be discontinued, and attributing all successful coping to the drug.

In addition to listening for an *overreliance* on medication, it is also important to listen for potential medication noncompliance. Occasionally, we see participants stopping medications because of unwanted side effects, negative beliefs about medications, or because they start to feel better. This puts them at greater risk for relapse. Therefore, it will be equally important to listen for red flags such as misconceptions about medications (e.g., fears of addiction, loss of control, or personality changes), negative past experiences with medications, and reluctance to be identified as a person with mental health problems.

At the end of the first session, the "Recognizing Anxiety" session, you will give the "Credibility and Expectations for Improvement" form to your participant, which asks about how much improvement is expected as a result of participating in the EXTENDED RELIEF program. Patients will mail this form to the study team without you seeing it to encourage them to fill it out honestly.

At the end of each session, you will fill out the "Understanding of Material" scale to give your impression of how well the patient "got it" in session. At the end of every session for which homework is assigned, you will fill out the "Homework Quality Scale" to evaluate how well the patient completed the at-home practice. At the end of sessions 4 and 12, you and the patient will both complete the "Working Alliance Inventory" to measure your perceptions of the therapeutic alliance. As with the credibility questionnaire, the patient will be given a stamped, addressed envelope to mail this directly to the study team.

You will keep the at-home practice forms until the end of therapy with that patient, but please forward the other scales to the study team, ideally weekly.

At-home Practice Exercises

Most importantly, you will assign at-home practice exercises every session. It may be helpful to photocopy these forms onto colored paper, so that it is easy for

the patient to distinguish white sheets (which they keep) from colored sheets (which they turn in to the therapist). For the first session in which a new skill is taught, end by completing an at-home practice sheet *together* with your patient. This will ensure that they understand what is being asked of them, reassure them about the amount of time required to complete the assignment, answer questions, and trouble-shoot potential problems. Then provide them with additional sheets to fill out, one every day. All of the at-home assignments ask how much worry or anxiety was experienced that day on a scale from 0 (None) to 10 (A lot). This rating scale is used to describe how the participant was feeling on average (as opposed to at the worst moment) on that particular day, regardless of what skill is being worked on.

Some patients have difficulty with the numeric scale to rate anxiety on a daily basis. The scale should be, 0 = No anxiety, 10 = a lot of anxiety, i.e., the most anxiety that they have experienced **in the last few months**. This should ensure that participants use the full scale, rather than assuming that the higher numbers are beyond their own experience of anxiety. It is often helpful to ask patients to remember the situation in which they were feeling the most anxiety over the last few months, and use how they felt in that situation as a "10". If a patient resists using the numbers, it is fine to think about the scale in terms of words, including the patient's own words. The important point is that the level of anxiety on the right side should be only as high as that particular patient has been experiencing recently. All of the at-home assignments also ask participants to indicate situations, physical sensations, thoughts, and behaviors associated with anxiety that were experienced that day. Use these items as examples for future sessions.

Begin each session by reviewing the at-home practice assignments. Ask your participant how their practice went and whether they ran into any obstacles completing the practice. Always reinforce them for completing any part of the assignment. Ask what kinds of things they noticed before, during, and after their practice (or in general over the week if they did not practice) about their experience of anxiety and worry. If they did not complete the assignment, spend some time identifying obstacles and problem solving. This may include using motivational enhancement strategies if their non-compliance appears to be a function of ambivalence.

Some at-home practice tips are as follows:

- Ask your participant if s/he understands why we are asking them to do a specific task rather than explaining it or lecturing to him/her (e.g., "Why are we asking you to write down what thoughts you had when you were

anxious?"). Be sure to validate and reassure the patient without "spoon-feeding" and providing answers right away.

- In general, follow the rule of three. If your participant does not understand a concept after going over it with a real-life example at least three times, make a specific suggestion or move on to the next topic.

- Remember to use examples the participant brings into session and reinforce completion of the at-home practice exercises.

- If your participant does not complete the at-home assignments, it is important to explore reasons for this. This is also true if patients do not take their escitalopram.

If incomplete at-home practice appears to be due to a lack of understanding, at the beginning of the session, complete a blank sheet along with your participant (as you did at the end of the previous session). This way, the patient will have an opportunity to complete the form with your coaching. In addition, you may encourage your participant to call you during the week with any additional questions.

If incomplete at-home practice appears to be due to a lack of motivation, try some motivational interviewing techniques. This may pose more of a problem in the context of a medication maintenance study; if they are already feeling better they may have less motivation to change. If so, roll with resistance; acknowledge that attending weekly therapy and practicing new skills for coping with problems and symptoms takes time and energy. "What I'm asking you to do is really hard and takes a lot of work. Why would you want to do it?" "Why now?" Work on developing a sense of discrepancy between what life is like now and how your participant would like life to be. Work with ambivalence: "on the one hand, you say you'd like to learn to relax, but on the other hand, you can't spare the time to practice relaxation. What does that tell you?" Put the responsibility on the patient: "It's your decision whether to make changes or not." Do a decisional balance exercise (listing pros and cons of change).

Other strategies for improving homework adherence include:

- Praise your patient for doing something analogous to completing an assignment and point out the similarity between that behavior and an at-home exercise task.

- If a family member is available to attend a session with the patient, address this in the family session and encourage family members to appropriately provide support for the patient, particularly with completing the at-home practice exercises. Another idea would be to ask your patient about the value of having a family member simply remind him or her of the assignment.

- Try referring to homework as at-home "practice exercises," "daily assignments," "tasks," or something other than "homework" to reduce any negative associations with the term "homework."

- Encourage self-monitoring and self-reinforcement of at-home practice completion.

- Explore when and where your patient will do the at-home practice exercises. Have the patient describe what he or she will do to confirm understanding of the task. Suggest choosing logical, easily remembered times to complete the assignments.

- Ask your patient what might prevent him or her from completing the at-home practice exercises and use problem-solving methods to prevent possible obstacles.

- Explore your patient's self-efficacy for completing the at-home assignments by asking the patient to indicate how confident he or she feels about completing the exercise (e.g., on a scale of 0-100%), and explore the answer. Ask your patient to describe a challenging assignment (e.g., academic or job-related) that he or she completed in the past and explore what methods were used that he or she could use now.

- If necessary, call your patient during the week to check on at-home practice completion. This will provide support, structure, and prompts regarding the assignments.

- Remember to reinforce completion of the at-home practice exercises with acknowledgment and praise as soon as possible in session.

- Use shaping if needed. At first, reinforce approximate completion of at-home practice exercises and then gradually raise the standard for reinforcement.

- If the at-home practice exercises are not completed, show curiosity while exploring what happened and what could be done differently in the future.

Some additional tips regarding psychotherapy with older GAD patients

The quintessential older GAD patient:

- May not see worry itself as the problem, rather may see it as a natural reaction to problems or as a personality trait

- Worries about "real problems" (most often also about minor matters but this is not the hallmark of late-life GAD as it is in younger adults)

- May identify one problem as primary and may stay focused on that for weeks, or talk about a different problem each session

Common issues for the older GAD patient:

- Need for control/sense of lack of control
- Overdeveloped sense of responsibility
- Perfectionism
- Fear of negative affect

    - These often lead to things such as overinvolvement with family, overcommitment to activities, excessive cleaning, keeping busy as strategy to avoid negative affect, belief that failure to put others ahead of oneself is selfish

- After pharmacological treatment, somatic symptoms may have improved a lot, but worry tends to improve less. The problematic behaviors that have become habit often have not changed either.

- Older adults with GAD often have limited insight that doesn't necessarily improve over the course of therapy; the patient frequently remains "stuck", not realizing that their need for control or overinvolvement is a problem

- Many older adults with GAD have an irrational fear of medications, even after successful treatment with them. The therapist can use this to increase motivation to learn skills to manage anxiety, but must also attempt to challenge the beliefs and encourage making an informed choice about discontinuation (after study completion) and reinitiation if needed.

- Other older adults with GAD may combine a lack of perceived personal control with a fear of anxiety and worry, leading them to be skeptical about their ability to cope without medications.

Behavioral Manifestations in the Older GAD Patient

- Avoidance often takes the form of not going to doctors, keeping busy to avoid "thinking too much," and procrastination

- Other "avoidance" strategies (i.e., to avoid negative affect) include:
    - Checking locks, blood pressure, etc.
    - Overcommitment to activities and overinvolvement with family

Common Issues in Therapy in the Older GAD Patient

- Many older adults have misconceptions about psychotherapy or mental health treatment (e.g., due to media depictions like Bob Newhart, "The Snake Pit," or "One Flew Over the Cuckoo's Nest"). It may be helpful to refer to this process as "tutoring" or "coaching" rather than psychotherapy.

- Similarly, some believe that they must understand the problem before they can solve it (e.g., by delving into early childhood experiences that could explain their anxiety). They have already been introduced to the medical model in the open-label escitalopram phase and it's fine to use that model and also introduce a learning model of anxiety and worry.

- Some patients argue or use overly long question and answer sessions about didactic material (e.g., "what's the difference between worry and anxiety? Then what is depression?") as an avoidance strategy. Don't spend too long on it; it's not that important.

- Patients often see an increase in anxiety as they try new behaviors. This is not only normal, it is actually a sign that the behavior is one they need to work on.

- Some participants may get a little depressed partway through treatment, particularly if they've gotten better and are introspective enough to recognize that their whole life might have been different if they had gotten help sooner. Validate your participant's experience – it is an understandable reaction to be sad about missed opportunities. Also encourage them to look to the present and future by thinking about what they can do now that they couldn't have done a few months ago, when they were still very anxious.

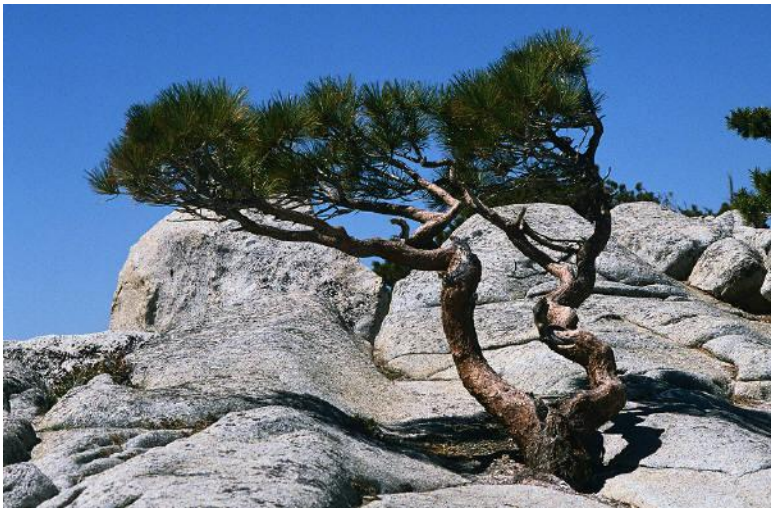
Some Additional Points Regarding Medication

- If your patient seems ambivalent about taking medications, consider showing his/her Hamilton scores over the course of taking medications to demonstrate how they have been helpful; follow-up with traditional motivational interviewing techniques.

- Talk to your patient about what s/he believes is helping him/her get better. If they attribute all of their improvement to medication, discuss what else might need to happen to boost improvement (i.e., review the purpose of augmenting medications with CBT). You can point out that CBT strategies can help reduce anxiety above and beyond medications, especially right before, during, or after stressful situations. If they attribute all their gains to therapy, point out how medications have been helpful in an effort to prevent premature termination of medications.

- Some patients may experience an increase in symptoms during the maintenance phase. Toward the end of the 16 regular sessions, forecast this for your patient and discuss strategies for how they can cope (i.e., which skills they will use). You may point out any fluctuations they experienced during the first 28 weeks of their participation in the study to make the point that symptoms happen and are not catastrophic. You may even give them an index card that says "When I feel the symptoms I can…" on one side with skills listed on the back. If the patient or an assessor notices an "early warning sign" of relapse, you will see your patient for booster sessions. Be sure to look for signs that the patient wants to immediately get back on drugs and encourage them to use their strategies for several weeks before deciding to return to medications.

Recognizing Worry and Anxiety
(2 Sessions)



**Time Note: Plan to take approximately 10-15 minutes to review the agenda, PSWQ, and introduce the program at the beginning of the session; plan to allow approximately 15 minutes at the end to summarize the session, explain and assign homework, and schedule your next session if necessary. Get through as much of the Recognizing Worry and Anxiety content as you can during the remaining half of the session, but don't rush through it. You will have a total of TWO sessions to get to know the participant and his or her anxiety symptoms.

Session Outline:
1. Set the agenda and administer PSWQ
2. Introduce the EXTENDED RELIEF program
3. Get to know your participant
4. Learn about your participant's anxiety
5. Assign at-home practice
6. Administer Expectations and Credibility Questionnaire (session 1)

1. Agenda and PSWQ

Explain to the participant the session components you intend to cover today and ask if s/he has anything they would like to add. Ask the patient to complete the Penn State Worry Questionnaire (PSWQ) and explain that you will be using it over the course of therapy to track progress.

If the patient endorses all 1's or all 5's, let the patient know that you will be talking more about the reasons for monitoring worry and anxiety and how to use that scale to do that.

2. Introduction to the EXTENDED RELIEF Program

Provide your participant with a copy of the EXTENDED RELIEF Study binder, including only the first chapter of the workbook. You should use the workbook to orient your participant to the material you will be reviewing. Points to cover in this section include:

- Your role as counselor – like a teacher or coach
- Appointment cancellation procedure
- Your contact information
- What to expect from treatment (treatment format, session structure, etc.)

3. Getting to Know You

In this section, ask questions of your participant in order to get to know him/her better. Questions to ask include:

- What kinds of problems are you coping with?
- What are your most significant reasons for getting help with worry or anxiety right now?
- What stressful experiences have you dealt with in the past, and how did you cope with them?
- What types of treatment for anxiety have you had?
- How do you feel about taking anti-anxiety medication? What is your goal for the future with respect to medication?

Obtaining historical information is important because patients are often feeling better after 12 weeks of escitalopram treatment, and therefore the goal of treatment is not so much on alleviating current symptoms as preventing future symptomatic exacerbations. Finding out about the stressors the person has experienced in the past and the typical way he/she has dealt with them will provide grist for a therapy in which more effective coping skills are taught. Pay attention for any problems that might resurface in the near future (health or family issues). Also listen for evidence of the patient's coping style, particularly subtle patterns of avoidance.

It is important to cover the questions about anxiety and treatment. Find out whether the patient has had previous experience with psychotherapy, and if so, what it was like. If patients have had supportive or psychodynamic therapy in the past, it is important to point out the differences from a skills-based therapy and ask for the patient's thoughts about this. Be sure to validate any concerns or negative

reactions (e.g., it seems rigid, etc.). If this is an issue, make sure to touch base with the patient regularly and acknowledge any lingering doubts or concerns.

In terms of medication, discuss with the patient their feelings, positive and negative, about medication. Suggest that the patient consider this period as a window in which they can learn skills to help them manage their anxiety should they choose to discontinue medications in the future. Let the patient know that if they do discontinue medications and find that they are not able to manage their anxiety, they can always return to medications, but this program is designed to help provide them with additional alternatives in order to make an informed choice.

Refer the patient to the manual for general information about anxiety and offer to answer questions during the next session.

4. Your Own Anxiety

In this section, you will teach your participant about the three types of "symptoms" that signal anxiety, physical sensations, thoughts, and behaviors, and how they interact with one another. Use the diagram on page 7 of the Patient Workbook to illustrate the relationships among the components. The best way to approach this is to ask the participant to describe the time in the past week that they felt most anxious. Have the participant write the situation, sensations, thoughts, and behaviors in the workbook.

Ask the patient why becoming more aware of anxiety symptoms might be helpful. Reasons include: 1) knowing when they need to engage in coping skills, 2) observing anxiety can provide a sense of distance from it, 3) recognizing variability helps patients understand that anxiety doesn't stay high forever, 4) learning triggers, including situations or times of day/week/year, that are associated with higher (or lower) anxiety levels, can help make anxiety more predictable, and 5) allowing a patient to see that he/she is improving, which can increase motivation for therapy.

5. Assign At-home Practice

You will then introduce the at-home practice exercises for this week. Be sure to emphasize the need for your participant to fill out the form *every day*, rather than saving them up and filling them all in by memory at the end of the week. Explain thoroughly how to do so, then have the patient complete one form with you.

All of the at-home assignments ask how much anxiety was experienced *on average* that day on a scale from 0 (None) to 10 (A lot). To anchor the scale, you

can ask your participant about the most anxiety-provoking situation they have experienced in the past couple of months, and define how they felt in that situation as a "10". Get anchors for the least anxiety-provoking situation as a 0 and a mid-level situation as a 5. If patients talk in the abstract, ask them to close their eyes, imagine themselves in a specific situation, and describe what they are feeling in their body, what they are thinking, and what they feel an impulse to do. These anchor points allow the patient to compare a new situation with a known situation and ultimately provide a shorthand way of communicating about anxiety with the therapist.

All of the at-home assignments also ask participants to notice the situations, physical sensations of anxiety and anxious thoughts and behaviors that were experienced over the week. Take note of these and use them as examples during future sessions. The teaching point for the "Recognizing Anxiety" at-home practice exercises is that the more your participant is able to learn about his/her anxiety, the better s/he will be able to manage it.

One good way to end every session is to ask the participant to summarize what was covered, e.g., "If you had to describe what we did today to a friend or family member, what would you tell them?" Ask your patient to review the material in the binder and write down what s/he learned in the space provided.

6. Administer Credibility and Expectations for Improvement (session 1)

At the end of session 1, you will give the "Credibility and Expectations for Improvement" form to your participant along with a stamped, addressed envelope to be mailed to the investigator. Make clear that you will not be seeing this form, so the patient is encouraged to be honest.

Optional Session: **Anxiety and the Family**

** Therapists should encourage participants to bring a significant other to one session, ideally session 3. This person should be a spouse/intimate partner, adult child, or other close family member (in our experience, friends are not as helpful); whose relationship with the patient is supportive; and who sees the patient frequently (at least once a week). Unsupportive people should not be invited. If no family member is available, this module can be skipped.

Goals for this topic:

1. Provide the family member with information about anxiety
2. Gather collateral information about the patient's anxiety symptoms and functioning
3. Solicit help and support for the patient in completing the treatment

Patients are often hesitant to invite a family member, so if this is the case, the therapist should plan to do some motivational interviewing during sessions 1 and 2 about the benefits to the patient of having someone help them in their desire to make changes in their life. In our experience, it is very helpful, so if patients have a spouse or adult children living in the area and the relationship is reasonably good, they should be strongly encouraged to bring someone in.

If a family member does accompany a patient to a session, the therapist should also plan to speak to the family member by phone at approximately session 7 and session 12 to discuss changes they have noticed, areas that they believe may still be problematic, and their own role in facilitating the patient's treatment (e.g., reminding them to practice skills).

In general, it is important to balance the "air time" between the patient and family member during this session. Try not to let anyone talk for more than 5 minutes before giving the other person time to respond. If it turns out that the relationship is conflictual, do not let the session move into a forum for airing grievances or get diverted into a couple's counseling session. If you have to, ask both parties to describe their own anxiety symptoms (rather than have the family

member talk about the patient) if that is the only alternative to listening to accusations or blame.

1. Information about Anxiety and Treatment

Explain to the participant and his/her significant other the session components you intend to cover today and ask if s/he has anything they would like to add. The patient should not fill out a PSWQ during this session.

Explain to the family member why the patient is participating in this program (because he or she has symptoms of GAD). It is very helpful to ask the patient to present what they have learned about anxiety to their family member. The therapist can supplement this information (for example, by showing the three component model diagram).

2. Information About the Patient's Anxiety

Ask the family member what symptoms they notice when the patient is feeling anxious or worried. Check in with the patient to see whether they agree. The therapist should quickly look over newly completed at-home practice sheets and pull any useful examples into the discussion.

3. Supporting the Patient in Treatment

The therapist should summarize the topics the program will cover, and how these relate to the three-component model. Emphasize the importance and value of doing at-home practice exercises and taking medication. Ask the family member and the patient how the family member might be able to help the process. Make sure to get agreement from the patient for whatever help the family member is planning to provide (i.e., family member should not provide reminders in a way that the patient interprets as nagging).

Provide the family member with the handout. Give the patient at-home practice sheets from the "Recognizing Anxiety and Worry" module.

Learning to Relax
(3 Sessions)

**Time Note: Plan to take approximately 15-20 minutes to review the agenda, PSWQ, and homework at the beginning of the session; plan to allow approximately 15 minutes at the end to summarize the session, explain and assign homework, complete the Working Alliance Inventory (after session 4 only), and schedule your next session if necessary. Get through as much of the Learning to Relax content as you can during the remaining half of the session, but don't rush through it. You will have a total of THREE SESSIONS to fully teach and practice the relaxation skills.

Session Outline:

1. Set the agenda
2. Review PSWQ and at-home practice
3. Understand the rationale for relaxation exercises
4. Practice three types of relaxation exercises:
    (a) Slow, deep breathing
    (b) Progressive muscle relaxation
    (c) Imagery
5. Assign at-home practice
6. Complete Working Alliance Inventory

1. Agenda

Explain to the participant the session components you intend to cover today and ask if s/he has anything they would like to add.

2. Review PSWQ and at-home practice

Go over the PSWQ and discuss any changes since last session. If no changes have occurred, choose 1-3 of the highest scoring items and ask what the patient might do to decrease that item to a score of 1 or 2.

Ask the patient whether they had any questions based on reading the workbook. Review at-home practices, checking in as to how they went and anything the participant noticed in completing them. Be sure the participant completed the exercises; if they were unable to do so, discuss obstacles and problem-solve ways to overcome them. Answer any questions the patient has regarding the practices.

Check in about medication compliance and discuss as necessary (e.g., obstacles, ambivalence, MI strategies, etc.)

Note that patients frequently have definite preferences among these techniques, finding one that works especially well or one that is aversive. As long as the patient has given each technique an adequate trial, he/she can focus on the one that works best and is not required to keep using something that doesn't work.

3. Rationale for Relaxation Exercises

You can start this session by asking the patient why performing relaxation exercises might be helpful. Refer back to the diagram linking physical sensations, thoughts, and actions to discuss that relaxation is one way to directly affect physical sensations. Also point out that relaxation can be used to deal with any unpleasant symptoms that may emerge if medications are discontinued, and also with insomnia.

4. Relaxation Exercises

PMR should be covered in both relaxation sessions, starting with 16 muscle groups in session 2, and decreasing to 2-4 groups in session 3. You may cover breathing and imagery in sessions 2 or 3, depending on time. Make sure you have covered all three techniques before session 4; session 4 should be devoted to review and practice rather than learning new material. You will get a prerecorded CD or audiotape with a breathing exercise, the 16 group PMR exercise, and the imagery script.

Prior to beginning any of the following exercises, ask your patient to rate his/her anxiety/tension/distress on a scale of 0 - no anxiety to 10 - the most anxiety

they've experienced over the past couple of months. Once you have completed the exercise, ask him/her to give this SUDS (subjective units of distress) rating again.

(a.) Diaphragmatic breathing (5-7 minutes)

Find out whether the patient breathes from the chest or abdomen by asking them to put one hand on the chest and the other hand on the abdomen and breathe normally. Ask the patient to notice which hand moves more, the one on the chest or the one on the abdomen? Explain briefly that the body is designed to breathe from the abdomen, and learning to breathe that way can decrease anxiety.

Script:

Get comfortable, close your eyes and place one hand on your abdomen and the other on your chest. Take one long, deep breath in through your nose and silently count to three. While you breathe in, focus on using your abdomen and feel it rise with your hand as your lungs fill with air. Hold your breath for a few short moments, think the word "RELAX", and then exhale through your mouth while silently counting to three. Feel the hand on your abdomen fall as you exhale the air from your lungs. Repeat 10 times and then notice how you feel. As you practice this skill, you can gradually increase the count to slow your breathing.

(b) PMR: 16 muscle groups (30 minutes)

Tell the patient that the next exercise involves learning to tense and then relax various muscle groups. Explain that there is both a mental and physical component to the exercise: the physical part of PMR involves tensing muscles and then relaxing them. The mental part of PMR involves paying attention to the sensations of tension and relaxation. Ask the patient why both of these parts might be helpful. Tensing the muscles first actually helps relax them, since it is normal for muscles to relax after being tensed. It will also help the patient identify when he or she is tense vs. relaxed, which helps increase awareness of anxiety. Let the patient know that he or she will start by learning how to tense and release 16 different muscle groups; later this will broken down into fewer muscle groups to make it easier to incorporate into daily life.

Remind the patient that it is important to try to concentrate on what he or she is experiencing and feeling in your body, but that if his or her mind is wandering, not to be concerned; this is perfectly normal. The patient should just take a second and refocus on how his or her body is feeling.

Let the patient know that this exercise should not hurt. If he or she has arthritis or other joint or muscle pain or a past injury, he or she can just imagine

tensing muscles, rather than actually tensing them. When it's time to relax, just release whatever tension is left and concentrate on feeling even more relaxed.

Script:

In a moment, I will instruct you to tense a specific area of your body. Only tense the muscles enough to notice the difference from relaxation; you should not be straining or tightening them more than a little bit. You want to hold that tension for about 10 seconds, then release it and focus on the area, for about 20 seconds, until I instruct you to tense again. Pay attention to the difference between how your muscles feel when they are tense and when they are relaxed.

Now get into a comfortable position and take a few slow deep breaths. Watch me and do the exercises just like I do. We'll start with your feet and work your way up.

1. Now build up the tension in your lower legs by flexing your feet and pointing your toes toward your upper body. Feel the tension as it spreads through your feet, your ankles, your shins, and your calf muscles. Feel the tension spreading down the back of the leg and into the foot, under the foot and around the toes. Focus on that part of your body for 10 seconds… Now release the leg tension… Let your legs relax heavily onto the floor. Feel the difference in the muscles as they relax. Feel the release from tension, the sense of comfort, the warmth and heaviness of relaxation. Relax the muscles for 20 seconds.

2. First, build up the tension in your upper legs by pulling your knees together and lifting your legs off the chair. Focus on the tightness through your upper legs. Feel the pulling sensations from your hop down and notice the tension in your legs. Focus on that part of your body for 10 seconds… Now release the tension and let your legs drop heavily down on to the floor. Let the tension disappear. Focus on the feeling of relaxation. Feel the difference in your legs. Focus on the feeling of comfort for 20 seconds.

3. Now build up the tension in your stomach by pulling your stomach in toward the spine. Feel the tension. Feel the tightness and focus on that part of your body for 10 seconds… now let the stomach go – let it go further and further. Feel the sense of warmth circulating across your stomach. Feel the comfort of relaxation (20 seconds).

4. Now build up the tension around your chest by taking a deep breath and holding it. Your chest is expanded and the muscles are stretched around your chest -- feel the tension around your front and your back. Hold your

breath (10 seconds)… Now slowly let the air escape and breathe normally, letting the air flow in and out smoothly and easily. Feel the difference as the muscles relax in comparison to the tension (20 seconds).

5. Build up the tension in your lower arms by making fists with your hands and pulling up on the wrists. If your nails are long, press your fingers against your palms to make fists. Feel the tension through your lower arms, writsts, fingers, knuckles, and hands. Focus on the tension – notice the sensations of pulling, of tightness. Hold the tension for 10 seconds… Now release the tension and let your hands and lower arms relax onto your lap, with palms facing down. Focus your attention onto the sensations of warmth in your hands and arms. Feel the release from tension. Relax the muscles for 20 seconds…

6. Now, build up the tension in your upper arms by pulling the arms back and in toward your sides. Feel the tension in the back of the arms, radiating up into your shoulders and back. Focus on the sensations of tension. Hold the tension for 10 seconds… Now release the arms and let them relax heavily down. Focus on your upper arms and feel the difference compared to the tension. Your arms feel heavy, warm, and relaxed. Relax for 20 seconds.

7. Moving up to your shoulders, imagine your shoulders are on strings being pulled up toward your ears. Feel the tension around your shoulders, radiating down into your back and up into your neck and the back of your head. Focus on that part of your body. Describe the sensations to yourself. Focus (10 seconds)… and then let the shoulders droop down. Let them droop further and further, feeling very relaxed. Feel the sense of relaxation around your neck and shoulders. Focus on the comfort of relaxation (20 seconds).

8. Build up the tension around your neck by pressing the back of your neck backwards and pulling your chin down toward your chest. Feel the tightness around the back of the neck spreading up into your head. Focus on the tension (10 seconds)… Now release, letting your head rest heavily against the bed or chair. Nothing is holding it up except for the support behind. Focus on the relaxation and feel the difference from the tension (20 seconds).

9. Build up the tension around your mouth and jaw and throat by clenching your teeth and forcing the corners of your mouth back into a forced smile. Hold the tension. Feel the tightness and describe the sensations to yourself (10 seconds)… And now release the tension, letting your mouth drop open

and the muscles around the throat and jaw relax. Focus on the difference in the sensations in that part of your body (20 seconds)…

10. Now build up the tension around your eyes by squeezing your eyes together for a few seconds (10 seconds)… and releasing. Let the tension disappear from around your eyes. Feel the difference as the muscles relax (20 seconds)…

11. Now build up the tension across the lower forehead by frowning, pulling your eyebrows down and toward the center. Feel the tension across your forehead and the top of your head. Focus on the tension for 10 seconds…and then release, smoothing out the wrinkles and letting your forehead relax. Feel the difference (20 seconds)…

12. Finally, build up the tension across the upper forehead by raising your eyebrows up as high as you can. Feel the wrinkling and the pulling sensations across your forehead and the top of your head. Hold the tension (10 seconds)…and then relax, letting your eyebrows rest down and the tension leave. Focus on the sensations of relaxation and feel the difference compared to the tension (20 seconds).

Now your whole body is feeling relaxed and comfortable. As I count from one to five, feel yourself becoming even more relaxed… One, letting all the tension leave your body. Two, sinking further and further into relaxation. Three, feeling more and more relaxed. Four, feeling very relaxed. Five, deeply relaxed. Now as you spend a few minutes in this relaxed state, think about your breathing. Feel the cool air as you breathe in and the warm air as you breathe out. Your breathing is slow and regular. And every time you breathe out, think to yourself the word "relax"…"relax"…"relax." Feeling comfortable and relaxed (two minutes)…Now as I count backwards from five to one, gradually feel yourself becoming more alert and awake. Five, feeling more awake. Four, coming out of the relaxation. Three, feeling more alert. Two, opening your eyes. One, sitting up and coming back to session.

Check in about patients' reactions to the exercise. If they had difficulty focusing, normalize this and instruct them to just gently refocus their attention on their bodies whenever they become distracted. And remember, this new skill gets easier with practice. Remind them that they will soon be learning shortened versions— 2-4 muscle groups—of this exercise.

(c.) PMR: 2-4 muscle groups (10 minutes)

To make relaxation more portable and useful in different situations, we are going to practice with a smaller number of muscle groups to reduce the time it takes to relax. This time, you will choose which muscles to tense and relax. We will use the same procedures as last week, focusing on tensing your muscles for 10 seconds, and then relaxing them for 20 seconds. As before, if you have pain, you can go easier in that area, or simply imagine tensing and releasing it.

Now tell me which areas (up to four) you tend to hold the most tension. *Therapists should jot this down and then proceed with PMR, using the above script for only the areas the patient has identified.*

(e.) Imagery (5-7 minutes)

Imagery is a relaxation technique that everyone has used at some point in his or her life. Daydreaming and remembering pleasant experiences are examples of imagery. Your imagination and tapping into your own experiences are hallmarks of imagery. This relaxation strategy can be very effective at calming stress and reducing anxiety. To maximize the relaxing benefits derived from imagery, it is very important to mentally construct an elaborate scene that you find appealing and peaceful. This can be a place you have actually been or a place you have only imagined. Be sure to include all your senses when constructing an image. Ask yourself these questions as you practice: What do I see? What do I hear? What do things feel like to the touch? What do I smell? What can I taste?

Let me know when you have a scene in your mind so that we can practice. Now, get comfortable, close your eyes, and give yourself permission to relax. Just follow my voice and remember to make your images as elaborate and realistic as possible, using all of your senses.

<u>Script:</u>

In front of you is a path to your special place. Walk slowly to your special place. As you walk, you notice that you are becoming calmer and less tense, you have left your worry and anxiety behind. The temperature is very comfortable. Look around. Feel yourself becoming more relaxed. What do you see? Notice how everything looks, where things are. *(pause)* What do you hear? *(pause)* Is there anything in front of you? *(pause)* Go ahead and reach out and touch it. Notice how it feels in your hand. You are feeling safe and calm, there's nothing that concerns you.

You have reached your special place. What's under your feet? How does it feel? Take a few more steps. Look around. What's above you? *(pause)* Do you hear anything? *(pause)* Do you hear anything else? *(pause)* Look around again.

(pause) Go ahead and touch what's in front of you. Notice the texture. *(pause)* Now, look around again. Look as far as you can see. *(pause)* What do you see? *(pause)* Can you hear anything? Do you smell anything? Taste anything?

Sit or lie down in your special place. You are very calm, very relaxed. Pay attention to what you see, what you hear, feel, taste, and smell. Stay here a while, knowing that you are safe and comfortable, and relaxed. *(3-5 minutes)*

Memorize the sights, sounds, feelings, tastes, and smells of this place. You can return here to relax any time you like. Now stand up, and walk back on the same path as before. Slowly open your eyes as you reach the end of your path. Remember that you can go back any time you want to.

Explain to the patient that they may also insert this pleasant image any time they catch themselves worrying. Some people like to imagine a big, red STOP! sign whenever they notice themselves worrying, and then insert their pleasant image in its place.

5. Assign at-home practice

Introduce the at-home practice exercises for this week. If the patient had any difficulty filling out the forms last week, have him/her complete one form with you. The teaching point for the relaxation exercises is that practice is needed to develop and master relaxation skills. Patients should start by practicing in a quiet, undistracted setting, but should move toward using the briefer forms of relaxation (2-4 muscle group PMR, breathing) during stressful situations throughout the day.

Remember to end session by asking the participant to summarize what was covered, e.g., "If you had to describe what we did today to a friend or family member, what would you tell them?" Ask your patient to review the material in the binder and write down what s/he learned in the space provided.

6. (Session 4): Administer Working Alliance Inventory

At the end of session 4, you will give the "Working Alliance Inventory – Client Version" form to your participant along with a stamped, addressed envelope to be mailed to the investigator. Make clear that you will not be seeing this form, so the patient is encouraged to be honest. You will also complete the WAI-Therapist version and return that to the investigator.

Positive Action
(3 Sessions)

**Time Note: Plan to take approximately 15-20 minutes to review the agenda, PSWQ, and homework at the beginning of the session; plan to allow approximately 10 minutes at the end to summarize the session, explain and assign homework, and schedule your next session. Get through as much of the Positive Action content as you can during the remaining half of the session, but don't rush it. You will have a total of THREE SESSIONS to fully teach and practice the problem solving skills.

Before session 8, the therapist should call the patient's family member, if the patient brought one to session. Discuss with that individual any changes he/she has noticed and areas on which further work is still needed. Reinforce the family member for supporting the patient in their at-home practice and other efforts to manage anxiety.

Goals for this topic:
1. Set the agenda
2. Review PSWQ and at-home practice
3. Understand the role of behavior in worry and anxiety
4. Learn techniques for changing unhelpful behaviors or solving problems
5. Changing behavior to reduce worry
6. Assign At Home Practice

1. Agenda

Explain to the participant the session components you intend to cover today and ask if s/he has anything they would like to add.

2. Review PSWQ and at-home practice

Go over the PSWQ and discuss any changes since last week. If no changes have occurred, choose 1-3 of the highest scoring items and ask what the patient might do to decrease that item to a score of 1 or 2.

Ask the patient whether they had any questions based on reading the workbook. Review at-home practices, checking in as to how they went and anything the participant noticed in completing them. Be sure the participant completed the exercises; if they were unable to do so, discuss obstacles and problem-solve ways to overcome them. Answer any questions the patient has regarding the practices.

Follow up on last session by discussing ways in which the patient has applied relaxation techniques to everyday life and stressful situations. Ask whether they have found specific techniques helpful in specific situations and how they will continue to utilize these skills in the future.

Check in about medication attitudes and compliance and discuss as necessary (e.g., overreliance, obstacles, ambivalence, MI strategies, etc.).

3. Understanding the relationship between behavior and worry or anxiety

Note that this module is deliberately flexible to allow for working on specific behaviors or solving life problems. You will likely have gotten a sense of any major life problems the patient is coping with or may need to cope with in the near future; you should plan to attack these head on. For example, if a patient is describing serious conflict with a spouse, don't be afraid to ask whether the patient is considering ending the marriage, and if so, to use making the decision about whether to stay or leave the problem to work on.

Begin this module by asking the patient how worry and behavior are related and explain that this module focuses on identifying and changing unhelpful behaviors associated with worry. Refer back to the diagram of interacting thoughts, feelings, and behaviors in the first chapter of the Patient Workbook.

Ask your participant to describe a time when worry or anxiety led to doing something unhelpful. Ask what impact this behavior had on his/her anxiety and his/her relationships. Although it is good to use Socratic questioning to prompt the patient to recognize his or her own unhelpful behaviors or problems rather than telling the patient what needs to change, **the therapist should suggest a problem to work on if the patient has limited insight about a problem that seems significant** (do not ignore the "elephant in the room"). You may want to refer back to any behaviors mentioned by the family member if they attended the first session.

Ask questions about how this behavior has been helpful or unhelpful in both the short and long run.

4. Techniques for changing unhelpful behaviors

Explain that the first step in changing unhelpful behaviors is to identify them. Ask your participant to think about his/her own unhelpful behavior. Ask if they are not doing some things enough or doing other things too much? Are there things they do to avoid feeling anxious or worried? Have friends or family members pointed out anything they do that is unhelpful? With the patient's information, you pick a serious life problem that the patient is not coping with effectively.

Once your participant has identified some of his/her unhelpful behaviors or problems, ask which one s/he would most like to work on during the coming week. The therapist may need to work with the patient to make this specific and measurable. For example, if the patient wants to "be more organized," the therapist should ask questions like, "If you could do just one thing that would make you feel more organized, what would it be? If I were watching you, how would I know you were being more organized?"

If a patient is avoiding dealing with what the therapist believes is a significant problem, the therapist should open a discussion with the patient about the pros and cons of using the time in therapy to work on that problem. You can assure a patient that it is not your role to insist on any particular course of action, but rather to give the patient a safe environment and new skills to think about problems and potential problems that lead to worry and anxiety.

The second step is to think about other things s/he could do instead. Have the patient brainstorm and write down in the Patient Workbook as many options as he or she can think of, without judging them. You may need to "prime the pump," but most of the work of generating options should be done by the patient. Remember, brainstorming means generating EVERY possibility, no matter how unlikely.

The next step is to select the best alternative. If the problem or the options are complicated, this might involve listing advantages and disadvantages of several or all the options, using a separate sheet of paper. For more simple problems, it is probably sufficient to simply list options. The patient should select the one best option and make a plan for doing it, including a schedule. Some GAD patients "do too much" by trying to do all the options they list, so encourage your patient to do only one thing at a time. Have the patient write the plan in the Workbook.

Therapists must balance the need to allow the patient to generate his/her own solutions with the need to ensure that the ultimate solution is workable. It is easy for anxious patients to avoid dealing with serious problems, but it is not helpful for the therapist to contribute by trying to put a band-aid on an unreasonable situation. Remember, there are always alternatives. Our goal is to help our often inflexible, avoidant patients see them.

The last step is to do it and see how it worked. If it didn't work, go back to the list and try a different alternative.

5. Changing behavior to reduce worry

Many patients will have long-standing behavior patterns that cause problems, such as getting overcommitted to activities. For these patients, it is important to help them see how the specific problems they are dealing with now may be part of this "big picture." Give the patient an index card and write the "big picture" problem on it (e.g., "I get too busy"). Then have them write down alternatives for when situations like this come up in the future (e.g., "don't start any new projects until I have finished one that I'm working on now," "just say no," "take a 30 minute rest break every 2 hours," etc.). Throughout the rest of therapy, point out any other examples of these problems and encourage the patient to use these strategies to solve them.

Validate that it isn't easy to make changes or break old habits. Predict that acting differently will be difficult and possibly stressful. Reassure the participant that they will be learning skills to cope with any worry or anxiety that comes up (e.g., relaxation they learned over the past 3 sessions). Encourage either taking "baby steps" or tackling the whole problem at once—it is up to the individual to decide what will work best. Ask what has worked in the past and what makes sense in the current situation.

However your participant decides to tackle problem solving, encourage him/her to identify at least one action s/he can take *every week* between now and the end of therapy that promotes positive action/healthy behavior change.

If your participant seems ambivalent about change, use motivational enhancement techniques to identify benefits and drawbacks to change versus staying the same. Encourage participants to think of it as an experiment and test out whether changing an unhelpful behavior makes a difference.

6. Assign at-home practice

Introduce the at-home practice exercises for this week. If the patient had any

difficulty with the forms last week, have them complete one form with you. The teaching point for the "Positive Action" exercise is that once your participant is able to change unhelpful behaviors, they will become less anxious and improve their relationships and quality of life.

Ask him/her to commit to taking one small step this week to promote a positive behavior change. Also encourage the patient to continue practicing relaxation in daily life.

Remember to end session by asking the participant to summarize what was covered, e.g., "If you had to describe what we did today to a friend or family member, what would you tell them?" Ask your patient to review the material in the binder and write down what s/he learned in the space provided.

Changing Your Thinking
(3 Sessions)

**Time Note: Plan to take approximately 15-20 minutes to review the agenda, PSWQ, and homework at the beginning of the session; plan to allow approximately 10 minutes at the end to summarize the session, explain and assign homework, and schedule your next session. Get through as much of the Changing Your Thinking content as you can during the remaining half of the session, but don't rush through it. You will have a total of THREE SESSIONS to fully teach and practice the cognitive restructuring skills.

Before session 12, the therapist should call the patient's family member, if the patient brought one to session 1. Discuss with that individual any changes he/she has noticed and areas on which further work is still needed. Reinforce the family member for supporting the patient in their at-home practice and other efforts to manage anxiety.

Session Outline:
1. Set the agenda
2. Review PSWQ and at-home practice
3. Identifying and challenging negative thoughts
4. Dealing with maladaptive schema
5. Assign at-home practice
6. Working Alliance Inventory (session 12)

1. Agenda

Explain to the participant the session components you intend to cover today and ask if s/he has anything they would like to add.

2. Review PSWQ and at-home practice

Go over the PSWQ and discuss any changes since last week. If no changes have occurred, choose 1-3 of the highest scoring items and ask what the patient might do to decrease that item to a score of 1 or 2.

Ask the patient whether they had any questions based on reading the workbook. Review at-home practices, checking in as to how they went and anything the participant noticed in completing them. Be sure the participant completed the exercises; if they were unable to do so, discuss obstacles and problem-solve ways to overcome them. Answer any questions the patient has regarding the practices.

Ask about ways in which the patient has applied relaxation techniques to everyday life and stressful situations. Ask whether they have found specific techniques helpful in specific situations and how they will continue to utilize these skills in the future.

Also asking the patient if they followed through with their committed action for healthy behavior change. If they did not, discuss obstacles and brainstorm solutions. For patients who are working on major problems, time devoted to cognitive restructuring will need to be balanced with time devoted to continued Positive Action. Similarly, some patients may have difficulty with the abstract thinking skills required in cognitive therapy; it is appropriate under these circumstances to devote a higher proportion of time to behavioral change.

Check in about medication compliance and discuss as necessary (e.g., obstacles, ambivalence, MI strategies, etc.). Begin discussing with the patient how they think the coping skills they have learned so far might be helpful in combination with medication or if medication is discontinued. Pay attention to signs that the patient is developing a sense of self-efficacy with respect to managing his or her own anxiety and worry. A good question to ask is, "On a scale of 0% to 100% confident, how confident are you that you are able to manage your anxiety and worry?" Answers below 100% should prompt additional discussion, e.g., "What would help you go up 5 points on that scale?"

3. Identifying and challenging negative thoughts

Start this section by referring back to the 3-component model, and explain that one excellent strategy for reducing anxiety is learning how to think differently. Explain that this is not just "the power of positive thinking;" rather, it is important to think more *accurately* because we know that anxious thoughts are often *inaccurate* and *distorted*. Use examples of thoughts that the patient has already

articulated in session or on homework forms. Ask the patient to generate other examples, if possible, but it is usually best for the therapist to provide examples to start with because patients often have difficulty identifying thoughts. Make sure to elicit thoughts related to the most serious current worry.

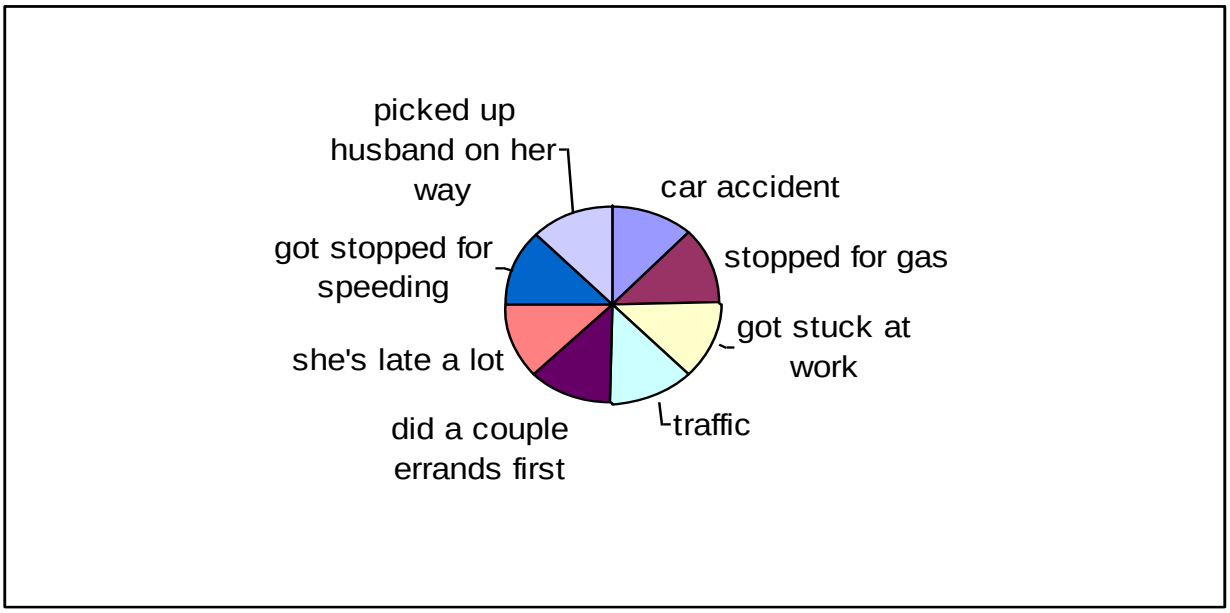
The Patient Workbook describes three types of negative thoughts: Fortune Telling (overestimating the risk), Catastrophizing, and "Should" Statements. These are the most common types of thoughts associated with anxiety. Other types of negative thoughts that are more closely associated with depression are listed in the table below. Therapists should identify and label negative thoughts the patient has expressed, even if they do not completely fit the examples of Fortune Telling, Catastrophization, or "Should" Statements.

Category	Definition
All-or-Nothing Thinking	Viewing a situation as two distinct categories rather than a continuum (also called black & white thinking)
Fortune Telling	Predicting the future negatively without considering other possible outcomes
Disqualifying the Positive	Telling oneself that positive experiences don't count
Emotional Reasoning	Assuming that because one feels or believes something so strongly, it must be true
Labeling	Attaching a global, extreme, negative label to oneself or others
Magnification/Minimization	Magnifying the negative &/or minimizing the positive
Mental Filter	Paying undue attention to a single negative detail instead of seeing the whole picture
Mind Reading	Believing that one knows what others are thinking
Overgeneralization	Making global negative conclusions that go well beyond the current situation
"Should" Statements	Holding fixed ideas about how the world "should," "ought to," or "must" be
Personalization	Seeing oneself as the cause of negative external events for which one is not necessarily responsible

<u>Challenging overestimation of risk</u>

The Pie Chart technique works best for thoughts overestimating the risk of a negative event. Ask the participant to rate how anxious that thought typically makes them on a scale of 0-10 (SUDS rating). Then use the Pie Chart Method to

generate alternative outcomes. To use the pie chart method, start with a circle and draw a slice for the negative outcome the patient is worrying about. Then generate all the other possible outcomes. See the example diagram below for the thought, "My daughter is 20 minutes late for dinner, what if she had a terrible car accident?!"



Once you have generated numerous alternatives, explain that prior to the exercise, the participant considered only the possibility of the car accident, feeling 100% certain that was the explanation, and of course, feeling anxious as a result. Then ask your participant what they think now. Lead them to the conclusion that there are several reasons she might be late and the likelihood she was fatally injured is actually quite small. In addition, you may want to point out that situations like this are *out of our control*, and worrying about them won't change their outcome. Generate an alternative, more accurate thought to replace the original anxious thought. For example, "There are dozens of reasons she may be late and worrying about it isn't going to help." Then ask your participant what their SUDS level is in response to this new thought and point out how it has changed from their original SUDS rating.

If a patient has a serious problem with a likely bad outcome (e.g., the terminal illness of a loved one), it is still possible to work on negative thoughts if you focus on the consequences to the individual. For example, you could use the pie chart technique to demonstrate that one option is "after he dies, I will die of grief," "I will never experience a moment of happiness again as long as I live," "I will be extremely sad for a while and will miss him forever," "Eventually I will be able to enjoy some aspects of my life," "I will share stories about him with my grandchildren," "Other people get over grief in time, so it is likely that I will too,"

etc. In this example, it's clear that none of the options are 100% positive, which is only to be expected, but it's also clear that there are still a range of possible outcomes, not all of which are 100% bleak.

The biggest danger in this technique is for someone to start generating examples of negative outcomes without any that are more neutral or positive. The best way to handle this is to make the exercise very specific about one particular thought. So if the thought is "after my husband dies, I will fall apart," keep the focus on the patient's emotional state ("falling apart") rather than allowing the patient to list all of the possible negative consequences of her husband's death ("I will fall apart," "I won't be able to do my finances", "I won't have a social life," etc.). Separate pie charts can be performed for the different problem domains (e.g., financial: "I will mess up the finances so badly I will lose my home," "I will bounce a couple of checks," "I will spend a lot of time and get frustrated," "I will hire a tax person to help me" etc.).

<u>Challenging lack of confidence in coping:</u>

For catastrophizing thoughts, identify a specific thought and ask for a SUDS rating. It is often helpful to use the most catastrophic possible outcome of a problem or situation the patient is dealing with. Then encourage them to generate all the ways in which they could cope if this worry thought came true (you may add your own as well).

For instance, using our previous example, let's say a loved one has a terminal illness and your participant has the thought, "this is a tragedy I will never get over." Validate that this loss would be very painful. Then ask your participant all the things s/he could do to get through it, listing these things in the workbook.

HOW I COULD COPE

1. Go to a bereavement support group
2. Go to church
3. Talk to a pastor or therapist
4. Lean on my children
5. Lean on my friends
6. Create a memorial in his name

Again, ask him/her to generate an alternative, more accurate thought. For example, "It would be very difficult for a while and I would miss him/her but using all my resources, I would eventually be ok. Besides, worrying won't prevent this." Ask for a SUDS rating after generating the new thought and point out how it has changed from the original thought.

Have your participant complete this exercise again with another worry thought, asking for the SUDS rating pre and post.

Summarize that effective coping thoughts remind us that feared outcomes are not as likely to occur as we think and we have the ability to handle the situation.

4. Dealing with Maladaptive Schema

You will likely know by now whether your patient struggles with an underlying maladaptive schema. The most common of these among older adults with anxiety are Need for Control, Responsibility, and Perfectionism. Discuss with your patient whether any of these apply to him/her and try to increase level of insight. It is important to acknowledge that these long-standing thought patterns were developed for a reason: either they made sense or were adaptive at some point. The question is whether the cost of holding them in terms of worry/anxiety is higher than the benefits they provide.

5. Assign at-home practice

Introduce the at-home practice exercises for this week. If the patient had any difficulty filling out the forms last week, have him/her complete one form with you. The teaching point for the "Changing your Thinking" exercises is that once your participant is able to cope with negative thinking (i.e., worry) in a more accurate way, s/he will change the way s/he feels and become less anxious.

The at-home practice forms do not have specific techniques listed. Patients should be encouraged to challenge their thoughts using whatever technique is appropriate. A Pie Chart can be drawn on the back of the form, for example.

Warning: some patients who ruminate excessively may use these techniques as a way to reinforce rumination. If so, downplay cognitive restructuring and keep the focus on the continued Positive Action steps.

Encourage the patient to continue practicing relaxation in daily life. Also ask the participant to commit to at least one action they can take this week that promotes positive action/healthy behavior change.

Remember to end session by asking the participant to summarize what was covered, e.g., "If you had to describe what we did today to a friend or family member, what would you tell them?" Ask your patient to review the material in the binder and write down what s/he learned in the space provided.

6. (Session 12): Administer Working Alliance Inventory

At the end of session 12, you will give the "Working Alliance Inventory – Client Version" form to your participant again along with a stamped, addressed envelope to be mailed to the investigator. Make clear that you will not be seeing this form, so the patient is encouraged to be honest. You will also complete the WAI-Therapist version and return that to the investigator.

Supplemental Module (two sessions)
Increasing Pleasure

**This module is only to be covered if assessments completed during the 12 week open-label escitalopram phase indicate that it is necessary. Ask the Study Coordinator whether this module is required for each patient.

**Time Note: Plan to take approximately 15-20 minutes to review the agenda, PSWQ, and homework at the beginning of the session; plan to allow approximately 10 minutes at the end to summarize the session, explain and assign homework, and schedule your next session. Get through as much of the Increasing Pleasure content as you can during the remaining half of the session, but don't rush through it. You will have a total of TWO SESSIONS to fully teach and practice the behavioral activation skills.

Before session 12, the therapist should call the patient's family member, if the patient brought one to session 1. Discuss with that individual any changes he/she has noticed and areas on which further work is still needed. Reinforce the family member for supporting the patient in their at-home practice and other efforts to manage anxiety.

Session Outline:
1. Set the agenda
2. Review PSWQ and at-home practice
3. Understand how increasing pleasant activities can improve your mood
4. Generating a list of pleasant activities
4. Develop a plan and schedule
6. Assign at-home practice

1. Agenda

Explain to the participant the session components you intend to cover today and ask if s/he has anything they would like to add.

2. Review PSWQ and at-home practice

Go over the PSWQ and discuss any changes since last week. If no changes have occurred, choose 1-3 of the highest scoring items and ask what the patient might do to decrease that item to a score of 1 or 2.

Ask the patient whether they had any questions based on reading the workbook. Review at-home practices, checking in as to how they went and anything the participant noticed in completing them. Be sure the participant completed the exercises; if they were unable to do so, discuss obstacles and problem-solve ways to overcome them. Answer any questions the patient has regarding the practices.

Follow up on last session by asking the patient what they learned and whether/how they applied the techniques to their experiences over the past week. Ask whether practice was helpful and how they will ensure continued practice.

Ask about ways in which the patient has applied relaxation techniques to everyday life and stressful situations. Ask whether they have found specific techniques helpful in specific situations and how they will continue to utilize these skills in the future.

Also follow up on last session by asking the patient if they followed through with their committed action for healthy behavior change. If they did not, discuss obstacles and brainstorm solutions.

Ask about ways in which the patient is applying the cognitive restructuring techniques to worries as they arise.

Check in about medication compliance and discuss as necessary (e.g., obstacles, ambivalence, MI strategies, etc.). Continue to discuss with the patient how they think the coping skills they have learned so far might be helpful in combination with medication or if medication is discontinued. Pay attention to signs that the patient is developing a sense of self-efficacy with respect to managing his or her own anxiety.

3. Pleasant Activities and Mood

You can start by asking why it might be helpful to do pleasant activities even when you feel depressed and unmotivated. Ask what happens to a person's mood when they stop doing pleasant things because they feel depressed. Points to cover include:

- There is a relationship between mood and activity that goes both ways
- Engaging in pleasant activities is important to reduce depression
- Do not wait for motivation before engaging in pleasurable activities
- Activity itself will help improve mood and motivation for activity

4. Generating a List of Pleasant Activities

Ask patients what they have enjoyed doing in the recent past, even if they haven't been doing it lately. Use the list in the Patient Workbook as a starting point, but don't be constrained by it. The patient should come up with at least 10 activities that they could do in the next week, even if they haven't been doing them lately.

5. Developing a Plan and a Schedule for Pleasant Activities

Ask patients why planning and scheduling pleasant activities in advance is important. Points to cover in this section include:

- Importance of doing at least three pleasurable activities every day
- Planning and scheduling these activities in advance makes them more likely to happen, especially if the patient is feeling down or unmotivated.
- Plans should be as detailed as possible, again to increase the likelihood that they will be carried out

6. Preparing for termination

Starting at around session 12, you should begin talking about termination, if you haven't already. You can talk about what you've observed as you've worked with the patient and what you've enjoyed about working with the patient. Encourage the participant to share his or her feelings about therapy coming to an end. Elicit any concerns about the fact that medications may be tapered at the same time that therapy is ending.

7. Assign at-home practice

Introduce the at-home practice exercises for this week and have the patient complete one form with you. The teaching point for the "Increasing Your

Pleasure" at-home practice exercises is that it is important to do at least three pleasurable activities each day regardless of motivation, and planning and scheduling a time and place for each one makes it more likely to happen.

Encourage the patient to continue practicing relaxation in daily life. Ask the participant to commit to at least one action they can take this week that promotes positive action/healthy behavior change. Remind the patient to notice and challenge distorted negative thoughts.

8. (Session 12): Administer Working Alliance Inventory

At the end of session 12, you will give the "Working Alliance Inventory – Client Version" form to your participant again along with a stamped, addressed envelope to be mailed to the investigator. Make clear that you will not be seeing this form, so the patient is encouraged to be honest. You will also complete the WAI-Therapist version and return that to the investigator.

Remember to end session by asking the participant to summarize what was covered, e.g., "If you had to describe what we did today to a friend or family member, what would you tell them?" Ask your patient to review the material in the binder and write down what s/he learned in the space provided.

Supplemental Module (two sessions)
Facing Your Fears

**This module is only to be covered if assessments completed during the 12 week open-label escitalopram phase indicate that it is necessary. Ask the Study Coordinator whether this module is required for each patient.

**Time Note: Plan to take approximately 15-20 minutes to review the agenda, PSWQ, and homework at the beginning of the session; plan to allow approximately 10 minutes at the end to summarize the session, explain and assign homework, and schedule your next session. Get through as much of the Facing Your Fears content as you can during the remaining half of the session, but don't rush through it. You will have a total of TWO SESSIONS to fully teach and practice the exposure skills.

Before session 12, the therapist should call the patient's family member, if the patient brought one to session 1. Discuss with that individual any changes he/she has noticed and areas on which further work is still needed. Reinforce the family member for supporting the patient in their at-home practice and other efforts to manage anxiety.

Session Outline:
1. Set the agenda
2. Review PSWQ and at-home practive
3. Rationale for exposure
4. Establish a fear and anxiety hierarchy
5. Learn how to practice exposure at home
6. Assign at-home practice

1. Agenda

Explain to the participant the session components you intend to cover today and ask if s/he has anything they would like to add.

2. Review PSWQ and at-home practice

Go over the PSWQ and discuss any changes since last week. If no changes have occurred, choose 1-3 of the highest scoring items and ask what the patient might do to decrease that item to a score of 1 or 2.

Ask the patient whether they had any questions based on reading the workbook. Review at-home practices, checking in as to how they went and anything the participant noticed in completing them. Be sure the participant completed the exercises; if they were unable to do so, discuss obstacles and problem-solve ways to overcome them. Answer any questions the patient has regarding the practices.

Follow up on last session by asking the patient what they learned and whether/how they applied the techniques to their experiences over the past week. Ask whether practice was helpful and how they will ensure continued practice.

Ask about ways in which the patient has applied relaxation techniques to everyday life and stressful situations. Ask whether they have found specific techniques helpful in specific situations and how they will continue to utilize these skills in the future.

Also follow up on last session by asking the patient if they followed through with their committed action for healthy behavior change. If they did not, discuss obstacles and brainstorm solutions.

Ask about ways in which the patient is applying the cognitive restructuring techniques to worries as they arise.

Check in about medication compliance and discuss as necessary (e.g., obstacles, ambivalence, MI strategies, etc.). Continue to discuss with the patient how they think the coping skills they have learned so far might be helpful in combination with medication or if medication is discontinued. Pay attention to signs that the patient is developing a sense of self-efficacy with respect to managing his or her own anxiety.

3. Rationale for Exposure

If you have never performed exposure with a patient, make sure to seek supervision from an experienced therapist ahead of time. The general principles are easy, but developing a fear hierarchy and especially doing interoceptive exposure (for patients with panic disorder) can be challenging in practice the first few times.

Ask the patient why it might be important to put him or herself into a situation that causes anxiety. Points to cover include the fact that avoiding situations makes it less likely for the patient to learn that they are in fact not overwhelming and that the patient has the ability to cope with them. Explain that exposure treatment is a technique that is used to help people with things or situations that make them very anxious, that they might have been avoiding. This includes specific fears like fear of heights, blood, or animals, fear of meeting new people or taking part in a group, and panic attacks. The process of exposure involves putting the person in a feared situation while using coping skills to decrease anxiety to a more manageable level. The steps are:

- Make a list of situations that cause anxiety
- Begin with the least anxiety-provoking situation on the list
- Put yourself in the situation and stay there until anxiety decreases, using coping skills
- Work your way up the list to the most feared item
- Move from one level to the next only after your fear has decreased

4. Creating a List of Anxiety-Provoking Situations

You will need to guide your patient in creating a fear hierarchy, writing down items in the Patient Workbook. All items should relate to the same fear, and can include imaginal situations, photographs, TV shows, etc. as appropriate in addition to real life situations. Items should be specific and detailed. There should be at least 8 items on the list. Patients will rate each item on the list on a 0-10 scale of anxiety. Make sure some items on the list produce some moderate (6-7), and some relatively intense (8-10) levels of anxiety. Practice in-vivo exposures with your patient in session and ask him/her to continue this practice on his/her own outside of session.

A special note about panic: If the patient has panic attacks or panic disorder, you can use a technique called "interoceptive exposure", in which the patient exposes him or herself to the physical sensations associated with a panic attack. The patient will deliberately bring on these sensations in session, as well as during at-home practice. You can explain that panic attacks are a form of learned or conditioned fear. Bringing on panic-like sensations via

harmless activities that are under the patient's control teaches him/her that, while physical symptoms may sometimes feel uncomfortable, there is no logical reason to fear them. Repeated exposure to the sensations in the absence of catastrophe (e.g., death, heart attack, "going crazy") essentially extinguishes the conditioned fear of the physical symptoms.

Be sure to check with the study physician prior to conducting interoceptive exposures to make sure there are no medical contraindications to inducing dizziness, increased heart rate, or other physical changes. Also, take your patient's physical condition into account and use your judgment when choosing exercises.

Ask the patient what sensations they associate with a panic attack. Panic symptoms may include racing/pounding heart, sweating, shortness of breath/smothering sensations, chest pain/tightness, dizziness/lightheadedness/faintness, tingling/numbing sensations, chills, hot flushes, nausea, muscle tension/weakness, shaking, blurred/tunnel vision, or feelings of unreality/detachment.

Pick among the following to induce the most feared sensations:

Physical Sensation	**Interoceptive Exercises**
Dizziness, shortness of breath, tingling	Hyperventilate by breathing deeply and rapidly, forcing all air out with each exhale
Dizziness, disorientation	Turn the head from side to side as far and quickly as possible or spin around in swivel chair or while standing
Lightheadedness, smothering sensations	Blow up a balloon
Shortness of breath, smothering sensations	Breathe through a coffee stirrer while blocking the nose
Rapid heart rate, sweating	March or run in place (holding a chair if necessary to avoid falls)
Chest tightness, smothering	Hold the breath
Muscle tension, weakness, shaking	Tense all the major muscles and hold
Choking sensations	Tough the back of the tongue with a finger or tongue depressor
Blurred or tunnel vision	Stare at a light (40 watts or lower) for one minute then read a paragraph of small print
Feelings of unreality	Stare intensely at one's face in the mirror for several minutes

Conduct these exercises in session by first demonstrating it to your patient and then asking him/her to do it. While doing this, he or she should articulate the thoughts experienced during an actual panic attack (e.g., "I'm having a heart attack," "I'm going to die," etc.). Have patients provide regular SUDS ratings. Once anxiety levels get to at least a 7, the patient should begin engaging in coping skills while they are performing the activity. Continue to perform the activity, with coping skills, until anxiety falls to 3 or less. Activities like this would be included on the anxiety list for the patient to practice at home.

The second issue to address for patients with panic disorder is agoraphobia, or avoidance of situations in which he or she is afraid of having a panic attack or panic-like symptoms. These situations should be added to the list to be performed after some interoceptive exposure has been completed, again in order from least anxiety-provoking to most anxiety-provoking. Similar items with varying levels of intensity can be used (e.g., going to church and sitting in the back row near the door, sitting in the middle of the church on the aisle, sitting in the middle of a pew, sitting in the middle of a pew in the front row). Finally, patients should practice bringing on the panic symptoms while in the feared situations (e.g., hyperventilating in church, etc.).

Patient should expose themselves to the feared stimuli they listed on their hierarchies (physical sensations, places, things, or situations) over and over until they no longer experience the symptoms, things, or situations as scary.

5. Practicing Exposure at Home

Help the patient problem-solve exactly how to do the exercise with the least anxiety-provoking item on the list. If possible, do the exercise in session. The patient should practice at home with the same item at first.

The steps for home practice are as follows:

- Start the practice session by relaxing for about ten minutes
- Put yourself in the situation that creates the least anxiety
- Rate anxiety on a scale of 0 to 10 when you first begin
- Stay in the situation until anxiety increases to at least 7
- Continue to stay in the situation until your anxiety reduces to a 3 or less
- Do not leave the situation (or stop) until your anxiety level decreases
- Repeat the exercise with the same situation every day until your anxiety never gets above a 3

- Then do the exercise with the next item on the list, repeating until the patient can do the exercise with the highest ranked item on the list while experiencing only mild to moderate anxiety.

6. Preparing for termination

Starting at around session 12, you should begin talking about termination, if you haven't already. You can talk about what you've observed as you've worked with the patient and what you've enjoyed about working with the patient. Encourage the participant to share his or her feelings about therapy coming to an end. Elicit any concerns about the fact that medications may be tapered at the same time that therapy is ending.

7. Assign at-home practice

Introduce the at-home practice exercises for this week and have the patient complete one form with you. The teaching point for the "Facing Your Fears" at-home practice exercises is that in order to reduce anxiety, your participant must put him/herself in the same anxiety-provoking situation every day until his/her anxiety level remains low.

Encourage the patient to continue practicing relaxation in daily life. Ask the participant to commit to at least one action they can take this week that promotes positive action/healthy behavior change. Remind the patient to notice and challenge distorted negative thoughts.

8. (Session 12): Administer Working Alliance Inventory

At the end of session 12, you will give the "Working Alliance Inventory – Client Version" form to your participant again along with a stamped, addressed envelope to be mailed to the investigator. Make clear that you will not be seeing this form, so the patient is encouraged to be honest. You will also complete the WAI-Therapist version and return that to the investigator.

Remember to end session by asking the participant to summarize what was covered, e.g., "If you had to describe what we did today to a friend or family member, what would you tell them?" Ask your patient to review the material in the binder and write down what s/he learned in the space provided.

Supplemental Module (one session)
Getting to Sleep

**This module is only to be covered if assessments completed during the 12 week open-label escitalopram phase indicate that it is necessary. Ask the Study Coordinator whether this module is required for each patient.

**Time Note: Plan to take approximately 15-20 minutes to review the agenda, PSWQ, and homework at the beginning of the session; plan to allow approximately 10 minutes at the end to summarize the session, explain and assign homework, and schedule your next session.

Before session 12, the therapist should call the patient's family member, if the patient brought one to session 1. Discuss with that individual any changes he/she has noticed and areas on which further work is still needed. Reinforce the family member for supporting the patient in their at-home practice and other efforts to manage anxiety.

Session Outline:
1. Set the agenda
2. Review PSWQ and at-home practice
3. Teach your participant some facts about sleep.
4. Review good sleep guidelines: "DROWSE."
5. Develop a plan to use good sleep skills.
6. Assign at-home practice

1. Agenda

Explain to the participant the session components you intend to cover today and ask if s/he has anything they would like to add.

2. Review PSWQ and at-home practice

Go over the PSWQ and discuss any changes since last week. If no changes have occurred, choose 1-3 of the highest scoring items and ask what the patient might do to decrease that item to a score of 1 or 2.

Ask the patient whether they had any questions based on reading the workbook. Review at-home practices, checking in as to how they went and anything the participant noticed in completing them. Be sure the participant completed the exercises; if they were unable to do so, discuss obstacles and problem-solve ways to overcome them. Answer any questions the patient has regarding the practices.

Follow up on last session by asking the patient what they learned and whether/how they applied the techniques to their experiences over the past week. Ask whether practice was helpful and how they will ensure continued practice.

Ask about ways in which the patient has applied relaxation techniques to everyday life and stressful situations. Ask whether they have found specific techniques helpful in specific situations and how they will continue to utilize these skills in the future.

Also follow up on last session by asking the patient if they followed through with their committed action for healthy behavior change. If they did not, discuss obstacles and brainstorm solutions.

Ask about ways in which the patient is applying the cognitive restructuring techniques to worries as they arise.

Check in about medication compliance and discuss as necessary (e.g., obstacles, ambivalence, MI strategies, etc.). Continue to discuss with the patient how they think the coping skills they have learned so far might be helpful in combination with medication or if medication is discontinued. Pay attention to signs that the patient is developing a sense of self-efficacy with respect to managing his or her own anxiety.

3. Facts About Sleep

You will start this module by providing your participant with general information about sleep. You should explain that poor sleep is not dangerous or incapacitating. It is important to explain that there are individual differences in the amount of sleep required to feel rested as well as normal age-related changes in

sleeping patterns. The teaching point is that by having your participant learn more about his/her sleep patterns, he/she will be able to determine if changes are normal or if factors such as anxiety are disrupting the sleep cycle.

4. Good Sleep Guidelines: "DROWSE"

Go through Patient Workbook to teach and review the six important rules to help guide your participant's mastery of good sleep, using the acronym "DROWSE":

Don't nap during the day.
Restrict the amount of time you spend lying in bed awake to 15 minutes.
Outdoor light every afternoon will help maintain your sleep/wake cycle.
Within 3 hours of bedtime, no alcohol, caffeine, heavy meals, or stimulating activities.
Sleep and sex are the only activities you should do in bed.
Establish a schedule for getting up and going to bed.

Ask the patient what he/she thinks about each point. Does it make sense? Are they doing it? If not, how could they incorporate these into their life?

5. Develop a Plan to Use Sleep Management Skills

You will assist your participant in developing a plan for good sleep in this section. Explain the following steps:

Understand the "DROWSE" guidelines
Keep the list of guidelines handy until they are learned completely
Do them!
Have patience with your plan for good sleep

6. Preparing for termination

Starting at around session 12, you should begin talking about termination, if you haven't already. You can talk about what you've observed as you've worked with the patient and what you've enjoyed about working with the patient. Encourage the participant to share his or her feelings about therapy coming to an end. Elicit any concerns about the fact that medications may be tapered at the same time that therapy is ending.

7. Assign at-home practice

Introduce the at-home practice exercises for this week and have the patient complete one form with you. The teaching point for the "Getting to Sleep" at-home practice exercises is that the more your participant practices the "DROWSE" guidelines, the better he or she will sleep, and the more they will have a sense of control over their insomnia.

Encourage the patient to continue practicing relaxation in daily life. Ask the participant to commit to at least one action they can take this week that promotes positive action/healthy behavior change. Remind the patient to notice and challenge distorted negative thoughts.

8. (Session 12): Administer Working Alliance Inventory

At the end of session 12, you will give the "Working Alliance Inventory – Client Version" form to your participant again along with a stamped, addressed envelope to be mailed to the investigator. Make clear that you will not be seeing this form, so the patient is encouraged to be honest. You will also complete the WAI-Therapist version and return that to the investigator.

Remember to end session by asking the participant to summarize what was covered, e.g., "If you had to describe what we did today to a friend or family member, what would you tell them?" Ask your patient to review the material in the binder and write down what s/he learned in the space provided.

Session 16
Maintaining Your Progress

**Time Note: Plan to take approximately 10-15 minutes to review the agenda, PSWQ, and homework at the beginning of the session; plan to allow approximately 15 minutes at the end to process termination. Use most of the session to elicit the patient's early warning signs of anxiety and make a plan if they recur.

Session Outline:
1. Set the agenda
2. Review PSWQ and at-home practice
3. Review progress in the EXTENDED RELIEF program
4. Develop a list of early warning signs and a plan for dealing with them
5. Discuss termination

1. Agenda

Explain to the participant the session components you intend to cover today and ask if s/he has anything they would like to add.

2. Review PSWQ and at-home practice

Go over the PSWQ and discuss any changes since last week. If no changes have occurred, choose 1-3 of the highest scoring items and ask what the patient might do to decrease that item to a score of 1 or 2.

Ask the patient whether they had any questions based on reading the workbook. Review at-home practices, checking in as to how they went and anything the participant noticed in completing them. Be sure the participant completed the exercises; if they were unable to do so, discuss obstacles and

problem-solve ways to overcome them. Answer any questions the patient has regarding the practices.

Follow up on last session by asking the patient what they learned and whether/how they applied the techniques to their experiences over the past week. Ask whether practice was helpful and how they will ensure continued practice.

Ask about ways in which the patient has applied relaxation techniques to everyday life and stressful situations. Ask whether they have found specific techniques helpful in specific situations and how they will continue to utilize these skills in the future.

Also follow up on last session by asking the patient if they followed through with their committed action for healthy behavior change. If they did not, discuss obstacles and brainstorm solutions.

Ask about ways in which the patient is applying the cognitive restructuring techniques to worries as they arise.

3. Reviewing Your Progress

The main goals of this session are the 3 Rs: Review, reinforce, and relapse prevention. Discuss the skills your participant uses most often (have them write these in the Workbook) and the situations in which they have been useful.

4. Planning for the Future

In this section, **emphasize that it is important to do something to manage anxiety before it gets out of control.** This means practicing skills frequently, even when feeling good.

The patient may soon be tapered off their medications. Regardless, anxiety and stressful life experiences fluctuate over time. Therefore, you should forecast a re-experience of anxiety symptoms. Elicit the patient's thoughts about this. Normalize this and remind them that anxiety is not dangerous, etc. Assist your participant with recognizing the situations and symptoms associated with anxiety that may serve as "early warning signs" for relapse. Have the patient write these situations or unpleasant physical sensations in their Workbook. Suggest that the participant discuss these signs with a trusted friend or family member. Develop a plan for what the participant will do if he or she notices any of these signs in the future.

Revisit medication issues and the importance of using skills as the first-line defense; we want them to do this for several weeks before choosing to go back on medications. Elicit any concerns about this, using Motivational Interviewing strategies if necessary.

Remind the patient that if he or she begins to experience a recurrence of anxiety at any time over the next 6 months, he or she should call you right away to schedule booster sessions.

Because this is potentially the last session in which you will see the patient, we do not give homework sheets after this session. However, patients should be encouraged to use their skills and notice for themselves how they are working.

5. Termination

You should take some time to discuss termination. You can talk about what you've observed as you've worked with the patient and what you've enjoyed about working with the patient. Encourage the participant to share his or her feelings about therapy coming to an end. Elicit any concerns about the fact that medications may be tapered at the same time that therapy is ending. It may help to frame this as "graduation," with an opportunity to put the hard work the patient has done into practice. Also discuss what options are available in terms of help in the future.

Remember to end session by asking the participant to summarize what was covered, e.g., "If you had to describe what we did today to a friend or family member, what would you tell them?" Ask your patient to review the material in the binder and write down what s/he learned in the space provided.