# Chapter 7: Home-based Treatments

## 7.1 Home-based Pencil Push-Up Therapy Group

- **7.1.1 Therapist Instructions**
- **7.1.2 Subject Instructions**
- **7.1.3 Weekly Phone Appointments and Office Visits after Masked Exams**
- **7.1.4 Forms**
- **7.1.5 Treatment Compliance**
- **7.1.6 Maintenance Treatment**

## 7.2 Home-based Pencil Push-ups with Computer VT/Orthoptics Group

- **7.2.1 Therapist Instructions**
- **7.2.2 Subject Instructions**
- **7.2.3 Weekly Phone Appointments and Office Visits after Masked Exams**
- **7.2.4 Forms**
- **7.2.5 Treatment Compliance**
- **7.2.6 Maintenance Treatment**

## 7.3 Home-based Treatments - Therapist Instructions

- **7.3.1 Therapist Instructions - Pencil Push-up**
- **7.3.2 Therapist Instructions - HTS**

## 7.4 Home-based Treatments - Subject Instructions

- **7.4.1 Subject Instructions - Pencil Push-up (Pencil Push-Up Therapy Group)**
- **7.4.2 Subject Instructions - Pencil Push-up (Pencil Push-ups with Computer VT/Orthoptics Group)**
- **7.4.3 Subject Instructions - HTS**
- **7.4.4 Subject Instructions – HTS Accommodative Therapy**
Chapter 7 Home-based Treatments

7.1 Home-based Pencil Push-Up Therapy Group

The Home-based Pencil Push-up therapy group will be asked to practice a well-defined pencil push-up procedure at home. This procedure utilizes an alphabet pencil and an index card in the background to provide physiological diplopia control. While a physiological diplopia control is not universally used in standard clinical practice, it has often been recommended in the literature in order to ensure that the subject is not suppressing. Therefore, we believe that this is an important component of the procedure in order to ensure that the subject receives the maximal benefit while performing the pencil push-up procedure.

Subjects will be required to demonstrate their ability to perform the procedure before beginning pencil push-up therapy at home. They will be instructed to spend 15 minutes per day, five days per week working on the pencil push-up procedure.

7.1.1 Therapist Instructions

The therapist will use a standardized set of instructions to teach the subject how to do pencil push-ups. The instruction sheet can be found in section 7.3.1.

7.1.2 Subject Instructions

Subjects will also be given a written set of instructions on how to perform the pencil push-up procedure. The instruction sheet is located in section 7.4.1 of this chapter. The therapist will review this instruction sheet in detail at the first treatment visit and spend sufficient time with the subject at this visit to ensure that the subject has a complete understanding of the technique. The therapist will also review the pencil-push up procedure during the weekly phone appointments.

7.1.3 Weekly Phone Appointments and Office Visits after Masked Exams

Subjects in this group will have nine phone appointments with the therapist. The call will be scheduled for the same time each week and the subject will be compensated for his/her time on this call (similar to weekly office visits). During this call the therapist will discuss the past week’s therapy schedule and the subject’s compliance. The subject will be asked to provide the data recorded on his/her CITT-Pencil Push-up therapy home log form so that the therapist may record these data. The therapist will then provide suggestions about how to overcome any perceived obstacles in the treatment and also will encourage and motivate the subject. The therapist will answer any of the subject’s questions and spend the remainder of the time discussing the importance of daily therapy and compliance.

The therapist should make every attempt to emphasize compliance and question the subject about problems/issues with home or office therapy. However, the therapist should not initiate discussion about the subject’s symptoms. If such issues arise, the subject can be directed to the principal investigator for further discussion. The vision therapist/orthoptist should not have access to the subject’s binder specifically results from the masked examinations. During weekly
meetings between the principal investigator and therapist to review subject progress, the discussion should be directed towards progress with therapy procedures and/or protocol issues.

Masked examinations will take place after 4 and 8 weeks of treatment. At these masked examinations, the masked examiner will evaluate the outcome measures. The therapist will then meet with the subject to discuss progress and answer any questions the subject might have about Pencil Push-up therapy. The subject will also demonstrate the Pencil Push-up technique to the therapist.

After the primary outcome examination (after 12 weeks of treatment), the therapist will meet with the subject if he/she has demonstrated sufficient improvement on the CI Symptom Survey to be considered “asymptomatic” (CI Symptom Survey <16). In these instances, the therapist will prescribe maintenance treatment (See section 7.1.6). Otherwise, the subject will be referred to a non-CITT doctor to receive an alternative CI treatment at no cost.

7.1.4 Forms

The forms used for Home-based Pencil Push-up therapy are:
1. CITT Pencil Push-up therapy therapist instructions (7.3.1)
2. CITT Pencil Push-up therapy subject instructions (7.4.1)
3. CITT Pencil Push-up therapy home therapy log form
4. CITT Pencil Push-up Phone Contact Form

Subjects will be required to keep a home log of the therapy completed each day. They will record the point at which they experience double vision (i.e., the distance the pencil is from the eyes when the subject can no longer converge and maintain fusion). Subjects will be asked to record this distance after every 5 minutes of pencil push-ups.

7.1.5 Treatment Compliance

We have enhanced the Home-based Pencil Push-up therapy in order to maximize compliance, motivation and retention in this group. While this protocol is more rigorous than that found in typical clinical practice, we believe that these changes are needed to achieve good compliance and retention in this group. First, subjects in this group will be scheduled for weekly phone appointments with the therapist. The subject and therapist will discuss the information the subject has recorded on the home log form regarding adherence and progress with treatment. Thus, the therapist will be able to monitor compliance/progress and motivate the subject on a weekly basis as in the other treatment groups. Second, similar to the office-based groups, the subjects will be compensated for their time for this call. Therefore, the study payments will be equal for all treatment groups.

7.1.6 Maintenance Treatment

Maintenance Pencil Push-up therapy is defined as 15 minutes of therapy, performed once per week from the 12-week masked examination until the 6-month follow-up visit. From the 6-month to the 12-month follow-up visit there will be no maintenance treatment. This pattern of maintenance treatment is consistent with standard care.
7.2 Home-based Pencil Push-ups with Computer VT/Orthoptics Group

The Home-based Pencil Push-ups with Computer VT/Orthoptics group will be asked to practice the same well-defined pencil push-up procedure as the Home-based Pencil Push-up group. In addition, they will work with the Home Therapy System (HTS) computer software at home. Subjects will be required to demonstrate their ability to perform these procedures to the therapist in the office before beginning therapy at home. Therapy should require a total of about 20 minutes per day (15 minutes for HTS and 5 minutes for pencil push-ups), five days per week.

7.2.1 Therapist Instructions

The therapist will use a standardized set of instructions to instruct the subject in how to do pencil push-ups and HTS (see sections 7.3.1 and 7.3.2).

7.2.2 Subject Instructions

Subjects will be given a written set of instructions which describe how to perform the pencil push-up procedure and HTS (see sections 7.4.2, 7.4.3, and 7.4.4). The therapist will review these instruction sheets in detail at the first treatment visit and at each weekly office visit (after each masked examination) to ensure that the subject has a complete understanding of the techniques.

7.2.3 Weekly Phone Appointments and Office Visits after Masked Exams

Subjects will have nine phone appointments with the therapist. The call will be scheduled for the same time each week and the subject will be compensated for his/her time on this call (similar to weekly office visits). During this call the therapist will discuss the past week’s therapy schedule and the subject’s compliance. The subject will be asked to provide the pencil push-up data recorded on his/her CITT-Pencil Push-up therapy home log form so that the therapist may record these data.

The subject should be reminded at each weekly call to save his/her data onto the data disk. The data disk must be brought to the clinic site for the Vision Therapist/Orthoptist to review at each masked examination. The data can be stored on a floppy disk, CD, or flash drive.

The therapist will then provide suggestions about how to overcome any perceived obstacles in the treatment and also will encourage and motivate the subject. The therapist will answer any of the subject’s questions and spend the remainder of the time discussing the importance of daily therapy and compliance.

Masked examinations will take place after 4 and 8 weeks of treatment. At these masked examinations, the masked examiner will evaluate the outcome measures. The therapist will then meet with the subject to discuss progress and answer any questions the subject might have about
pencil push-up therapy or HTS therapy. The subject will also demonstrate the pencil push-up technique for the therapist and bring in the data disk for HTS so that the therapist can review the subject’s HTS performance and compliance data. After the Vision Therapist/Orthoptist reviews the subject’s data, it must be copied and saved onto a computer at the Clinic Site as a back-up.

After the primary outcome examination (after 12 weeks of treatment), the therapist will meet with the subject. If he/she has demonstrated sufficient improvement on the CI Symptom Survey to be considered “asymptomatic” (CI Symptom Survey score <16) the therapist will prescribe maintenance treatment (Chapter 7.2.6). Otherwise, the subject will be referred to a non-CITT doctor to receive an alternative CI treatment at no cost.

7.2.4 Forms

Forms used for Home-based Pencil Push-ups with Computer VT/Orthoptics include the:

1. CITT Pencil Push-up Therapy therapist instructions (7.3.1)
2. CITT Pencil Push-up Therapy subject instructions (7.4.2)
3. CITT Computer VT/Orthoptics (HTS) therapist instructions (7.3.2)
4. CITT Computer VT/Orthoptics (HTS) subject instructions (7.4.3 and 7.4.4)
5. CITT Pencil Push-up with Computer VT/Orthoptics (HTS) Home Log Form
6. CITT Pencil Push-up Phone Contact Form

7.2.5 Treatment Compliance

Subjects will be required to keep a home log of the dates therapy was performed, the time spent performing therapy, and the levels achieved for each activity. The HTS data disk will provide both confirmation and a back-up of information for the computer therapy.

7.2.6 Maintenance Treatment

Asymptomatic subjects in this group will be prescribed maintenance therapy. Maintenance therapy for the Home-based Pencil Push-ups with Computer VT/Orthoptics group is defined as 15 minutes of therapy, performed once per week including 5 minutes of push-ups, and 10 minutes of HTS therapy from the 12-week masked examination until the 6 month follow-up visit. From the 6-month to the 12-month follow-up visit there will be no maintenance treatment. This pattern of maintenance treatment is consistent with standard care.
7.3 Home-based Treatments – Therapist Instructions

7.3.1 Therapist Instructions - Pencil Push-up

Equipment:

1. Alphabet Pencil
2. White index card
3. Centimeter ruler
4. CITT Pencil Push-up with Computer VT/Orthoptics Home Log Form

Procedure:

1. Have the subject stand or sit comfortably 6 to 8 feet in front of a wall. Attach the index card, oriented vertically, to the wall at eye level.
2. The subject should hold the pencil at arm’s length directly between his/her eyes and the card on the wall. When the subject looks at the small letter on the pencil, he/she should see one clear, small letter on one pencil and 2 cards in the background.
3. Ask the subject to slowly move the pencil towards his/her nose.
4. The subject should be looking at the small letter on the pencil, but also be aware of the 2 cards on the wall with his/her peripheral vision.
5. The cards should move apart and become smaller as the pencil approaches the subject’s eyes. If one of the cards disappears, have the subject stop moving the pencil and blink his/her eyes until both cards are present.
6. Ask the subject to continue looking at the small letter as he/she moves the pencil slowly towards his/her nose and to try and keep it clear and single for as long as possible. When the subject can no longer keep it clear ask him/her to continue to try and keep it single. When the subject can no longer keep it single, ask him/her to stop moving the pencil and try to get the letter back to one. At this point it is fine if the letter is one but blurry.
7. If the subject can get the letter one again, ask him/her to continue moving it closer to his/her nose. If the subject cannot get the two letters back into one, have the subject slowly move the pencil away from his/her nose until he/she can bring the two letters together.
8. Once the subject can make the letters one again, instruct him/her to continue moving the pencil closer to his/her nose. If the subject cannot get the letter back to one, have the subject start the procedure over at step 2.
9. Have the subject perform 5 minutes of push-ups and after completing measure the distance of the pencil to the brow, just above the nose. Record this distance.
10. The goal of the procedure is for the subject to get the pencil tip within 2 to 3 cm of his/her the brow, just above the nose on each push-up.

Subject Certification:
Before beginning Pencil Push-up therapy to be performed at home, the subject will have to demonstrate the ability:

1. To complete 5 minutes of push-ups
2. To measure the distance at which the subject experiences double vision (the break) after 5 minutes
3. To enter the results on the CITT Pencil Push-up therapy home therapy log form.
7.3.2 Therapist Instructions – HTS

Objective
To improve the subject’s ability to comfortably converge and diverge his/her eyes.

Equipment Needed
1. Computer
2. HTS program disk
3. Red and blue filter glasses
4. HTS Accommodative Flippers (Flipper 1, 2 and 3)

Procedure
1. At this first visit your goal is to demonstrate the use of the HTS program to the subject.
2. Therapy will include both fusional vergence and accommodative therapy,
3. Fusional vergence therapy will begin with the base-out therapy, followed by base-in therapy, auto slide vergence therapy, and jump ductions.
4. Accommodative therapy will be performed using the HTS accommodative program and using the HTS accommodative flippers.
5. To demonstrate HTS, select the “demo HTS” program.
6. Have the subject wear the red and blue glasses and select base out vergence and the therapy program will begin.
7. Instruct the subject to look at the large square with a smaller square inside that is “popping out.”
8. Ask the subject to press the arrow key that corresponds to the direction of the square. (i.e., push the left arrow key if the small square is on the left side of the larger square).
9. Tell the subject that if he/she correctly matches the location of the smaller square the computer will “beep” and increase the difficulty of the task. If incorrect the computer will “boop” and decrease the difficulty of the task.
10. Tell the subject that when the large box separates into two not to randomly push the arrow keys in various directions.
11. Instead, have the subject try to get the “feeling” of pulling the eyes together, crossing the eyes, or working harder until the boxes fuse together into one.
12. Have the subject practice for 3 minutes or until you feel the subject fully understands the procedure.
13. Now demonstrate the accommodative program. The subject wears the red and blue glasses holds the HTS Flippers marked “Flipper 1” before his/her eyes. Instruct the subject to move the arrow in the direction of the gap in the letter “C” on the screen.
14. Once the patient demonstrates an understanding of this procedure, instruct him/her to do this as quickly as possible.
15. Demonstrate how the computer program tracks progress from session to session.
16. Demonstrate how to find the “performance” component of the program and how to use this information to fill out the CITT Home-Based Pencil Push-ups plus Computer Orthoptics HTS log form.
17. Tell the subject that he/she will be required to bring in the data disk and HTS Flippers at each follow-up examination and that we will be able to see all the details of the therapy that was done at home.
7.4 Home-based Treatments – Subject Instructions

7.4.1 Subject Instructions - Pencil Push-up (Pencil Push-up Group)

Equipment:
1. Alphabet Pencil
2. White index card (supplied by study)
3. Centimeter ruler (supplied by study)
4. CITT Pencil Push-up therapy home therapy log form (supplied by study)

Procedure:
1. Stand or sit comfortably 6 to 8 feet in front of a wall. Attach the index card, oriented vertically (longest side pointing up and down), to the wall at eye level.
2. Hold the pencil at arm's length directly between you and the card on the wall while you look directly at the small letter on the pencil. You should see one clear letter, one pencil, and 2 cards in the background.
3. Move the pencil slowly towards your nose while concentrating on the small letter.
4. Keep looking at the small letter on the pencil, but be aware of the 2 cards on the wall in the background with your peripheral (side) vision.
5. As the pencil approaches you, the cards should move apart and may appear to become smaller. If one of the cards disappears, stop moving the pencil and blink your eyes until both cards are present.
6. Continue to look at the small letter while moving the pencil slowly towards your nose. Try and keep it clear and single as long as possible. When you can no longer keep the small letter clear, continue to try and keep it single as you move it closer. When you can no longer keep it single (it has become two), stop moving the pencil and try to get the letter back to one. If you cannot get the two letters back into one, slowly move the pencil away from you until you can bring the two letters together.
7. Once you can make the letters one again, continue moving the pencil closer to your nose. If you cannot get the letters back into one, start the procedure over at step 2.
8. Spend 15 minutes per day, five days per week doing this exercise. Do the pencil push-up technique for 3 sets of 5 minutes. After completing each 5 minute session, measure the distance of the pencil to your brow, just above the bridge of your nose. Record this result on your log form.

The goal of the procedure is to get the pencil tip within 2 to 3 cm of your brow, just above the nose.
7.4.2 Subject Instructions - Pencil Push-up (Pencil Push-ups with Computer VT/Orthoptics Group)

Equipment:
1. Alphabet Pencil
2. White index card (supplied by study)
3. Centimeter ruler (supplied by study)
4. CITT Pencil Push-up therapy home therapy log form (supplied by study)

Procedure:
1. Stand or sit comfortably 6 to 8 feet in front of a wall. Attach the index card, oriented vertically (longest side pointing up and down), to the wall at eye level.
2. Hold the pencil at arm's length directly between you and the card on the wall while you look directly at the small letter on the pencil. You should see one clear letter, one pencil, and 2 cards in the background.
3. Move the pencil slowly towards your nose while concentrating on the small letter.
4. Keep looking at the small letter on the pencil, but be aware of the 2 cards on the wall in the background with your peripheral (side) vision.
5. As the pencil approaches you, the cards should move apart and may appear to become smaller. If one of the cards disappears, stop moving the pencil and blink your eyes until both cards are present.
6. Continue to look at the small letter while moving the pencil slowly towards your nose. Try and keep it clear and single as long as possible. When you can no longer keep the small letter clear, continue to try and keep it single as you move it closer. When you can no longer keep it single (it has become two), stop moving the pencil and try to get the letter back to one. If you cannot get the two letters back into one, slowly move the pencil away from you until you can bring the two letters together.
7. Once you can make the letters one again, continue moving the pencil closer to your nose. If you cannot get the letters back into one, start the procedure over at step 2.
8. Spend 5 minutes per day, five days per week doing this exercise. After completing the 5 minute session, measure the distance of the pencil to your brow, just above the bridge of your nose. Record this result on your log form.

The goal of the procedure is to get the pencil tip within 2 to 3 cm of your brow, just above the nose.
7.4.3 Subject Instructions – HTS

Objective
To improve your ability to comfortably converge (cross your eyes) diverge (relax your eyes).

Equipment Needed
1. Computer
2. HTS program (supplied by the study)
3. Red and blue filter glasses (supplied by the study)

Procedure
1. The instructions for installation of the HTS are in the manual that is included with the software.
2. To launch the HTS program double click on the HTS icon that has been added to your Desktop screen.
3. The first time you use the HTS program you will be prompted to enter your name. Once your name has been entered it cannot be changed.
4. After entering your name you will be instructed to insert the KEY DISK. Your doctor will have already personalized your “KEY DISK” for your use. You only need to do this once.
5. Once the KEY DISK has been successfully loaded you will see the “Main Menu” screen.
6. Place the red and blue filter glasses over your eyes and click on the “Run Program” button and the therapy program will begin.
7. You should notice a large red square with a smaller square inside that is “popping out” towards you.
8. Push the arrow key that points in the same direction where the small square appears (i.e., push the left arrow key if the small square is on the left side of the larger square).
9. If you correctly match the location of the smaller square the computer will “beep” and the difficulty of the task will be increased. If you are incorrect, the computer will “boop” and decrease the difficulty.
10. When you reach the point where the large box separates into two, do not randomly push the arrow keys in various directions.
11. Repeat the procedure for the assigned practice time.
12. The computer program will keep track of your therapy from session to session. As you make progress, the computer program will automatically advance you to the next program. You simply need to select the “run program” button at the beginning of each session.

Your Therapy Goal
The computer program will track your progress and automatically advance you to more difficult procedures as you reach your goals.
7.4.4 Subject Instructions – HTS Accommodative Therapy

Objective
To improve your ability to comfortably focus and relax the focusing system of your eyes.

Equipment Needed
1. Computer
2. HTS program (supplied by the study)
3. Red and blue filter glasses (supplied by the study)
4. HTS Accommodative Flippers (Flipper 1, 2 and 3)

Procedure
1. After completing the first computer procedure designed to improve your ability to cross and relax your eyes, the computer program will automatically begin the focusing procedure.
2. For this procedure you must wear the red/blue eyeglasses and also use the HTS Flippers that were provided.
3. The computer program will tell you which Flipper to use (Flipper 1, Flipper 2, or Flipper 3).
4. Select the Flipper that the program suggests and hold it in front of your eyes so that you are looking through the red/blue glasses and the two lenses.
5. You will see a series of “C”s on the screen. You must move select the arrow key that corresponds to the open part of the “C”. For example, if the “C” is positioned so that the opening is on top, select the arrow key pointing up.
6. It is important to try and do this procedure as quickly as possible.
7. As you make progress, the computer program will tell you to select the next flipper.
8. If you correctly match the location of the opening of the “C” the computer will “beep”. If you are incorrect, the computer will “boop”.
9. Continue the procedure for the assigned practice time.
10. The computer program will keep track of your therapy from session to session. As you make progress, the computer program will automatically advance you to the next level and next Flipper. You simply need to select the “run program” button at the beginning of each session.

Your Therapy Goal
The computer program will track your progress and automatically advance you to more difficult procedures as you reach your goals.