CHAPTER 14

FITNESS TESTING

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14.1. INTRODUCTION

Exercise testing (maximal and submaximal) will be performed on a sub-group of subjects as part of the LIFE trial. The maximal graded exercise test (GXT) is performed following all other screening tests and before randomization. The primary research question to be addressed by performing this test is: Can a physical activity intervention in an elderly population improve indices of maximal/symptom limited cardiorespiratory fitness? Because the GXT test will be used to evaluate change of over time, clinic staff needs to strictly adhere to the GXT protocol in order to minimize test-retest variability and provide an accurate measurement of fitness change.

All testing will be conducted using a Lode Excalibur Sport cycle ergometer, an electronic, rate-independent ergometer, which will be routinely calibrated. The subjects will be required to practice on the cycle ergometer during the initial orientation session, providing they meet eligibility requirements and consent to participation in this study, i.e., provide signed informed consent.

14.2. SCHEDULE

A maximal GXT will be performed on all potential subjects at *baseline and following 6 months of intervention.*, following successful completion of all of the other screening tests (prior to final randomization).

14.3. REQUIRED EQUIPMENT, SUPPLIES AND PERSONNEL

Equipment:

- Heavy duty, electronic, rate-independent, cycle ergometer.
- 12-lead ECG with continuous on-screen monitoring of at least three leads.
- Metabolic Gas Measurement Cart
- A manual sphygmomanometer and extra long stethoscope for measurement of blood pressure (BP).
- A gurney or other comfortable flat surface for measurement of pre-test resting ECG.
- A space for subjects to dress/undress and have electrodes placed on their chest. Electrodes should be placed on the torso according to standard positioning for left arm, right arm, left leg, right leg, V1, V2, V3, V4, V5, and V6.
- Immediate access to a fully equipped crash cart and defibrillator. An Automatic External Defibrillator model is suggested if submaximal tests will be done without direct physician supervision. The crash cart must be routinely updated and the defibrillator tested each day before exercise testing.

Supplies:

- Stopwatch or other timer for determining total exercise time.
- Razor to shave hair.
- Acetone and gauze for cleaning the skin.
- 6-0 (220) sandpaper to gently abrade skin prior to electrode placement.
- High quality disposable exercise testing electrodes.
- Velcro waist belt to secure electrode wires tightly in place.
- Body stocking or mesh to secure electrode wires against the torso.
- Gowns should be available for female participants.

- Borg Rating of Perceived Exertion (RPE) scale (6-20) to assess participant symptoms; large enough to be read by exercising subjects. (Appendix A)
- List of standard ACSM stop criteria hung on/near the ECG machine, but not where the participant can see it (see Chapter 14, Appendix B).
- Snacks for participants post testing.
- ACSM Guidelines for Exercise Testing and Prescription, 6th Edition. Philadelphia: Lippincott Williams & Wilkins, 2000.
- List of your facility's emergency procedures and telephone numbers near the treadmill/ECG machine.

Personnel:

Qualified and experienced personnel are essential for obtaining valid data from the exercise test and the following standards are recommended:

- A physician with experience in exercise testing and emergency resuscitation procedures should be in the immediate area for all maximal GXTs. The PI or designated physician should be on call to evaluate any abnormalities that occur during the GXT. He/she can then evaluate this study in comparison to the max baseline test to determine if these changes were new and warrants further cardiovascular follow-up or other intervention.
- At least one American College of Sports Medicine (ACSM) certified Exercise Specialist (or equivalent) with BLS (Basic Life Support) or ACLS (Advanced Cardiac Life Support) certification that has passed central Look AHEAD training for this procedure.
- There should be two persons (one primary tester and one assistant) directly conducting exercise testing.

14.4. MAXIMAL GXT PROCEDURE

14.4.1. Helping the Subject to Relax

Clinic staff should explain what will happen during the test and answer any questions the participant may have. Encourage subjects to converse about previous exercise test experiences.

The staff should maintain a kind, friendly, calm and professional demeanor.

14.4.2. Participant Instructions

Participant should be given a set of instructions at the time the exercise test is scheduled and clinic staff may want to phone participants 24 hours prior to the appointment to review the participant instructions. A sample format of these instructions is provided in Appendix C.

- Individuals should not eat for 2-3 hours prior to testing, i.e., a small (≤ 8oz) water, juice, or non-caffeinated soda is permitted. Subjects should be instructed to avoid beverages with caffeine (e.g., coffee, tea, soda) prior to testing.
- Come to the test with shorts (or loose slacks), comfortable walking or running shoes (must tie or Velcro securely), loose T-shirt, towel/change of clothes (if not returning home after the test).

14.4.3. Pre-test Equipment Checks

- Check the operation of the defibrillator and the contents of the crash cart at the start of every day.
- Check operation of the ECG printer and monitor.
- Check ECG paper to be sure you can complete an entire test without changing.
- The cycle should be periodically calibrated accordingly to manufacturer maintenance schedules. Calibrate cycle ergometer
- The metabolic cart should be calibrated prior to each test.
- A log should be maintained at the site to document this procedure.

14.4.4. Pre-test Evaluation of the Subject

- After the subject has been seated for five minutes, two blood pressure readings should be taken (two minutes apart) and averaged for the GXT baseline blood pressure. If there is a 10 mmHg systolic and 6 mmHg diastolic difference between the two blood pressures, the blood pressure should be repeated until there are two blood pressures within these limits. It may be appropriate to obtain orthostatic BPs in participants with a prior history of orthostatic symptoms such as dizziness or syncope; the attending physician should decide if the participant can exercise safely. Obtain resting (supine) ECG. The physician should review the resting ECG and compare it to the most recent ECG, (i.e., baseline) prior to the GXT to evaluate for any new ischemic process or arrhythmia that might produce hemodynamic compromise.
- The physician should review the prior history, physical examination and laboratory tests, and obtain a history for any **new chest pain or changes in chest pain/discomfort or shortness of breath**, previous exercise tests, and changes in medications, orthopedic problems, acute illnesses (hospitalization) or change in chronic illnesses. To assist the sites in understanding when physician supervision may be appropriate, refer to the three tables in Appendix D.
- The physician should briefly examine the participant for evidence of congestive heart failure, arrhythmia, or significant valvular heart disease (especially aortic stenosis).

14.4.5. Skin Preparation and Electrode Placement

- Remove electric watches.
- Subject should be standing stripped to the waist (women may wear a sports bra if it does not interfere with electrode placement) and have shoulders straight and arms relaxed at sides.

- Use a razor to shave any hair (with subject's consent). If participants withhold consent to shave the hair, this will not allow adequate contact between the electrode and the skin. This may diminish the quality of the ECG and these tests should be interpreted with caution.
- Clean the area with gauze soaked with acetone.
- Mark the locations for the GXT electrodes.
- Gently remove outer epidermis by gentle abrasion with 6-0 sandpaper (#220) or Omni Prep.
- Carefully position and apply electrode firmly at the sites listed under section 14.3. Discard and replace any poorly adherent electrode.
- Attach electrode wire waist belt and untangle wires.
- Attach electrode wires to the proper electrode, always using the exact same order (**incorrectly applied electrodes or wires are the leading cause of poor quality or faulty ECG tracings**).
- Looping and taping electrode wires over the electrode itself will enhance the security of the connection.
- Use a body stocking or mesh to wrap and further secure all of the wires.
- **Remember: poor skin preparation and electrode placement or transposition or poor attachment of electrode wires are the leading cause of poor quality of faulty ECG tracings!**
- Replace loosely fitting T-shirt if participant requests.
- The staff will demonstrate and instruct the subject on the following:
  - Procedure for mounting/dismounting the bike.
  - Use of emergency signals and emergency stop system
  - Use of the Borg 6-20 RPE scale.
  - Procedure for obtaining BP while exercising.
  - Procedures for initiating and ending the test.
  - Outline of the procedure including the timing of stages and the expected increases in speed and grade.
  - Explanation of symptom-limited maximal effort and signs and symptoms of exercise intolerance (need for stopping); the

instructions for achieving a maximal effort are important if consistent data are to be obtained.

– *Subjects are told that they should give a maximal effort on this test. A maximal effort is one in which the subject pushes themselves until they believe that they have less than 30 seconds of effort remaining before they could not continue any further.* A rough guide is to determine the 85% of predicted maximal heart rate (220-age x 0.85) and subjects should reach or exceed this level to give assurance that a true maximal effort has been obtained. This 85% HRmax should be calculated and recorded on the GXT form as one of the goals or endpoints for a maximal test; however subjects should not be told of these endpoints. Rather, subjects should be instructed to give a maximal effort and to continue until the point of volitional fatigue or until they experience any signs or symptoms that were described earlier that would indicate that the test should be terminated (technicians should inform the subject of these criteria that would warrant stopping the test for safety reasons). The use of RPE is particularly important for individuals who are taking a beta blocker, with the standard or guide being an RPE (Rating of Perceived Exertion) of 18, 19, or 20 to reflect a maximal subjective effort. When anchored appropriately subjects not on a beta blocker should also achieve an RPE of 18, 19, or 20 at the point of volitional exhaustion.

14.4.6. Acclimation Test:

- Before any exercise tests are administered, subjects will be allowed to use the cycle ergometer, the mouthpiece for collecting gas samples, etc., so that they will be familiar with the procedures to be used during the exercise tests. This will occur during the orientation session or during one of the initial visits once subjects have given their informed consent.

14.4.7. Sub-maximal and Maximal GXT

- Each exercise tests will start at a low-tension level (15 W) and proceed in 2 minute stages until volitional fatigue. Each subsequent stage following test initiation will proceed in 15 W increments.
- During the entire protocol, gas exchange variables (VO2, CO2 production, ventilation, and respiratory exchange ratio (RER) will be recorded in a breath-by-breath manner and recorded and stored on a computer. Data will be subsequently exported in averaged 30 sec and 60 sec intervals. All measured parameters will be analyzed from using data from each completed minute of the exercise protocol.
- SBP and DBP will be measured at rest and during the last 30 sec at each power output. Heart rate will be measured directly from the ECG monitoring system.
- Ratings of perceived exertion (RPE) will be obtained using the Borg scale.
- Both steady-state submaximal and maximal values will be obtained for each test variable during each bike test.
- Testing will take place a baseline (pre-intervention) and 6-months (post intervention). The same maximal exercise test protocol will be used and the same gas exchange and cardiovascular variables will be measured.
- At the indicated time of termination (Recovery):
  - Stop the bike and record total exercise time and max RPE.
  - Help the subject lie down on the gurney immediately and get an immediate supine ECG and blood pressure.
  - Continue to check BP, pulse and 12-lead ECG every two minutes.
  - Continue to monitor recovery for a total of ten minutes.
  - The subject should then carefully stand to determine that they are safe to walk around without dizziness or other problems.
  - Inquire and indicate on the GXT form the subject's reason for stopping.

- Debrief subject and allow them to ask questions.
- Inform the subject that this maximal test may have been difficult for them, but the purpose is to ensure their safety; and also inform them that they will not have to repeat the maximal test at subsequent follow-up examinations.

- The criteria for achieving VO2max are RER >1.1, a plateau in VO2 (change of 100 mL · min-1 or less over the last 3 consecutive 30-sec of each exercise stage), and a HR within 10 beats · min-1 of the maximal level predicted by age. Those participants who do not meet these criteria will be classified as having reached their VO2peak, and subsequent data analysis will account for this factor.
- The following variables will be were measured during each test: VO2, pulmonary ventilation (VE), ventilatory equivalents for oxygen (VE·VO2-1) and carbon dioxide (VE·VCO2-1), and end-tidal partial pressure of oxygen (PETO2) and carbon dioxide (PETCO2). These parameters will be used to examine the wattage level where ventilatory threshold (VT) and respiratory compensation point (RCP) occur. VT will be determined using the criteria of an increase in both VE·VO2-1 and PETO2 with no concomitant increase in VE·VCO2-1. RCP will be determined using the criteria of an increase in both the VE·VO2-1 and VE·VCO2 and a decrease in PETCO2. VO2peak. Peak power output (W) will be chosen as the peak values observed during the last full minute completed during the cycling tests.

14.5. Contraindications for exercise testing (or reasons for RESCHEDULING)

The following contraindications are taken from the ACSM's Guidelines for Exercising Testing and Prescription, 6th edition.

New history or evidence of:

- Myocardial infarction (MI), unstable angina or pulmonary embolus.

- Evidence or history of hemodynamically significant aortic stenosis.
- Undiagnosed chest pain.
- Undiagnosed syncope.
- Recent illness or hospitalization likely to affect the testing effort/result, such as infectious illness (cold, influenza, pneumonia), surgery, etc.
- Abnormality of the lower extremity likely to affect the testing effort/result, such as strains or sprains.
- Recent change in medication likely to affect the testing effort/result such as significant increase in cardiac (i.e., beta blocker dosage) or other medications.
- Severe hypertension prior to testing ($\geq$ 200 mmHg systolic or $\geq$ 105 mmHg diastolic on repeat determination).
- Significant change in the previous (baseline) ECG consistent with **new:**
  - MI or ischemia.
  - Complete left or right bundle branch block or trifacicular block.
  - 2nd or 3rd degree heart block.
  - Wolfe-Parkinson-White.
  - Prolonged Q-Tc.
  - Atrial fibrillation/flutter.
  - Premature ventricular contractions (PVCs) that are multiform, in pairs, in runs or making up $\geq$ 25% of all beats.
  - Acute infectious disease (ideally the test would be rescheduled.)
- Physician's decision (must be specified as to why the test was not conducted).
- Any other type of an adverse event found prior to doing the test that result in the test not being done should be documented; a letter should be drafted to the Primary Care Physician with an explanation and recommendation.

14.5.1. Criteria for the Physician to Stop a GXT

The criteria for the termination of a graded exercise test are included in Appendix A (ACSM Guidelines for Exercise Testing and Prescription, 6th Edition).

14.5.2. Follow-up Letter from Attending Physician to Referral Physician For Abnormal Tests

Upon completion of the fitness test, a letter that explains the test results should accompany the report to the participant's physician. The following information should be included: 1) Interpretation of resting ECG (no contraindications to testing), 2) Who stopped the test (participant or MD), 3) Reason for stopping the test (i.e., reached goal/max or other), 4) Any arrhythmias (what type, frequency, runs), 5) Blood pressure response (good/not), 6) Pulse response (good/not), 7) Any significant ST changes, 8) Additional comments, 9) Overall interpretation (normal, borderline, abnormal), and 10) signature, preferably from the study MD. An example of the follow up letter is found in (Appendix J).

14.5.3. Follow-up Letter to Referral Physician to Report Symptoms

In order for participants to continue in the Lifestyle Intervention after having symptoms contraindicating exercise, a letter should be sent to the participant's physician recommending that the participant be referred for evaluation of the specific symptoms and to obtain approval. (See Appendix I for a sample letter, the baseline Maximal GXT and Appendix K for a sample letter for the follow-up submaximal GXT.)

14.6. EMERGENCY PROCEDURES

The professional staff conducting the maximal and submaximal graded exercise tests should have in place a printed emergency protocol to use in the event of an emergency. The emergency procedures should be practiced at least monthly to ensure a prompt and effective response. A record of these practice drills should be maintained by each site; the record should also indicate any deficiencies and how these have been corrected. This emergency protocol should describe the role of each professional, and the coordination with another emergency team (EMT) to ensure the continuation of care beyond the testing site. The emergency management plan should conform to the ACSM (2000) recommendations (pp.

283-294). We also recommend that all sites have a copy of this document as it contains information related to this chapter tables and other.

14.7. QUALITY CHECKS

Quality checks will include the following:

- Calibration of the cycle ergometer and metabolic cart as recommended by manufacturer. Each clinic should keep a log of the calibration procedures that are conducted.
- Calibration of the ECG for voltage/paper speed daily.
- Regular inspection of graded exercise forms for outliers and other errors by the coordinating center

14.8. INSTRUCTIONS FOR THE COMPLETION OF THE MAXIMAL GRADED EXERCISE TEST FORM

14.8.1. Participant Information

Place the participant ID label on the front page of the questionnaire in the indicated area. The date form completed should be the date of the exercise test. Record the gender and age of the participant.

Question 1: After the participant has been prepared for the ECG and other measurements, the resting ECG should be administered. The attending physician will evaluate the resting ECG and compare it with the participant's most recent ECG to determine if it is normal and if there have been any significant changes. Check the appropriate box and if there has been significant change from baseline, then describe the change.

Question 2: This question asks if there are any contra indications to the test. The contraindications to testing should be based on ACSM standards described above in section 14.5. If yes, list the reason.

Question 3: Check one box only. If the GXT was not performed or rescheduled list the reason.

Question 4: Asks you to list cardiac medications.

Question 5: Record how many hours it has been since the participant has last eaten food.

Question 6: Next, the resting blood pressures and heart rate should be determined. Two consecutive blood pressures should agree within 10mmHg/6mmHg for SBP/DBP respectively, or a third determination should be made. The form provides for up to three blood pressure measurements to be recorded. If the first two measurements are within 10mmHg/6mmHg, only these two measurements are to be recorded. If the two measurements are not within 10mmHg/6mmHg, perform a third blood pressure measure and record on the form. Note that only one resting heart rate is to be recorded and it should be the resting ECG heart rate.

Question 7: Using the formula on the form, calculate the estimated HRmax. 220 minus the individual's age. Multiply this by 0.85 to derive the HRmax goal for the maximal GXT and enter this on the form. This goal in the maximal GXT must be met or exceeded by all participants who are not currently taking beta blockers (as recorded on Question 4). Since beta blockers influence heart rates, the goal for participants taking these medications is based on a RPE goal of 20. Their RPE must meet or exceed 18 for the maximum GXT to be valid.

Question 8: Next, the participant will be introduced to the cycle ergomenter and allowed to pedal freely.

Question 9: Once the test has begun, record the HR, SBP, DBP, RPE at every 2 minutes until the test is terminated, either due to the participant's voluntary

request or due to one or more of the termination criteria. Indications for stopping should be noted, using the ACSM list in the Appendix A.

Question 10: The total exercise time should be noted and it includes the total minutes of the test plus the additional seconds in the final stage, the maximal heart rate during the test, and the maximal RPE.

Question 11: This question deals with the recovery stage of the test. Once the test is terminated, record the HR, SBP, DBP, and any additional comments for ten minutes. The purpose of these comments is to note anything unusual in the participant's recovery, i.e., chest pain, other discomfort or symptoms. If there are no adverse signs, the participant may be released.

Questions 1-11 on Summary Page: These questions summarize the Graded Exercise Test. Complete the eleven questions on the final page of the form regarding the pertinent information about the fitness test. This information will be communicated to the referring physician in a summary letter. These questions are designed to provide the referring physician with an interpretation about the participant's performance on the test, whether the responses were normal, and the safety of prescribing or continuing an exercise program in the Look AHEAD study.

Question 1: Asks for an interpretation of the resting ECG. Enter the appropriate interpretation. If normal, enter normal.

Question 2: Asks information on who stopped the test; the staff, the participant, the physician or GXT staff. Enter the appropriate answer.

Question 3: Enter the reason the maximal test was stopped.

Question 4: Asks that you describe any arrhythmias to include the type, frequency and runs. If there were no arrhythmias, enter none in all boxes.

Question 5: Asks you to enter the blood pressure response if the participant had an inappropriate response, explain what it was.

Question 6: Asks you to enter the heart rate response and if inappropriate, to provide details.

Question 7: Asks that you describe any significant ST changes. If no changes, enter none and enter if the participant had significant ST depressions. If there are other changes, describe the changes in the indicated box.

Question 8: The box provides space for any additional comments you may wish to record.

Question 9: Asks for the overall interpretation of the GXT test. Check the appropriate box and if abnormal, enter the reason.

Question 10: Summarizes the validity of the test.

Question 11: Asks if referral to the primary case physician was necessary. If yes, list the reason fro referral and inform the Look AHEAD PC so that a SAE form can be filled out if needed.

Question 12: The attending physician should sign the form and the technician and physician ID's should be entered in the appropriate places.

Questions 1-10 on Summary Page

These questions summarize the Graded Exercise Test. Complete the ten questions on the final page of the form regarding the pertinent information about the fitness test. This information will be communicated to the referring physician in a summary letter. These questions are designed to provide the referring physician with an interpretation about the participant's performance on the test,

whether the responses were normal, and the safety of prescribing or continuing an exercise program in the Look AHEAD study.

Question 1: Document the interpretation of the pre-exercise resting ECG.

Question 2: For tests when the subject achieves the desired termination points (80% of age-predicted max heart rate for subjects not on a beta blocker or RPE $\geq$16 for subjects on a beta blocker), box #2 should be checked indicated that the MD or technician terminated the test. Box #2 should also be checked if the MD or technician terminates the test early for safety or technical reasons. Box #1 should only be checked if the subject indicates they need to stop prior to achieving the desired submaximal termination points based on heart rate or RPE.

Question 3: Box #1 should be checked if the subject achieves the desired heart rate or RPE termination points. Box #2 should be checked for all other reasons that a test is terminated.

Question 4: Types, frequency, and runs of any arrhythmias should be documented.

Question 5: The interpretation of the blood pressure response during the GXT should be documented.

Question 6: The interpretation of the heart rate response during the GXT should be documented.

Question 7: ST changes are to be described. If there were no ST segment changes indicate “normal, N/A”.

Question 8: Document any additional comments related to this GXT.

Question 9: Indicate the overall interpretation of the GXT. If “abnormal” document the reason for this interpretation.

Question 10 and 11: Based on the GXT a clinical interpretation of the physician related to the safety for continuing exercise should be documented. This applies to all subjects regardless of their randomized group assignment, because some individuals in the DSE group may have undertaken an exercise program on their own.

- If, based on the GXT, there are no safety concerns for continuing the exercise program; box #1 "Eligible to continue exercise with no limitations" should be checked.
- If, based on the GXT, there are any abnormal responses that require follow-up with the subject's PCP, box #2 "Suspend exercise and refer to PCP" should be checked. For safety purposes, subjects that are in this category should be instructed by the clinic staff to suspend any exercise program that they may be participating in (both Look AHEAD and non-Look AHEAD exercise programs) until they receive clearance from their PCP to restart their program. The Program Coordinator should be notified so that appropriate documentation (e.g., letter to PCP [see Appendix K], intervention modification forms, etc.) can be completed according to the Look AHEAD protocol.

  NOTE: If the test is terminated prior to achieving the required submaximal termination criteria based on heart rate or RPE, the test will need to be repeated to assess fitness.
- If the test is terminated by the subject for no specific medical safety reason or because of technical failure of the testing equipment, the submaximal GXT needs to be repeated within ±30 days of the assessment anniversary date, which is consistent with the Look AHEAD protocol.
- If the test was terminated by the physician or technician for a medical safety reason that requires additional medical clearance, every attempt should be made to receive appropriate medical clearance and this submaximal test repeated within 60 days of the assessment anniversary date. However, in the event that this does not occur because extensive clinical evaluation/treatment are required, the submaximal test should be

repeated at the earliest possible time once medical clearance has been received.

Question 12: The attending physician should sign the form and the technician and physician ID’s should be entered in the appropriate paces.

Appendix A

RPE SCALE

6	
7	Very, very light
8	
9	Very light
10	
11	Fairly light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Very, very hard
20	

Instructions for the RPE Scale

These instructions should be read to the participant prior to the start of the GXT.

- You are now going to take part in an exercise test and you will be pedaling on an electric bike while we measure your response to exercise.
- During this test, I will also want to know how hard you are working so you will be looking at a scale containing numbers from 6 to 20 – these will be used to rate your perception of physical exertion.
- When you do this, I want you to think about the total feeling of exertion in your overall body, including your check, breathing, and muscles.
- When looking at this scale, I want you to think of a 6 as no exertion at all. So if you were to rate your perception of exertion right now – you would assign that a 6.

- Now I'd like you to think about the most exhaustive work you are capable of doing.
- When – you have reached your maximal level, are completely exhausted, and cannot continue the test for another 30 seconds, then you would rate that a 20. During this test today it is important that you go to the point of a maximal effort.
- It is important that we can see how your body responds to maximal effort so that we can develop a **safe** level of exercise for you in this study. This is the only time you will be asked to exert yourself to maximum in this study.

In summary,

- This test will start out slowly at a moderate level of effort.
- You will be asked to give a rating of perceived exertion every minute of the test.
- Remember, we just want you to think about the intensity of the exercise, and assign a number to how hard it feels. Start with any number that is appropriate as there is no right or wrong answer.
- The test will continue until you reach a maximal effort, and it is very important that you achieve a maximal effort on the test today.
    - We will know whether you have been able to achieve this based on your heart rate today, so be sure to give us a maximal effort.

APPENDIX B

Indications for Terminating Exercise Testing*

Absolute Indications

- Drop in systolic blood pressure of >10 mm Hg from baseline blood pressure despite an increase in workload, when accompanied by other evidence of ischemia.
- Moderate to severe angina.
- Increasing nervous system symptoms (e.g., ataxia, dizziness, or near syncope.
- Signs of poor perfusion (cyanosis or pallor).
- Technical difficulties monitoring the ECG or systolic blood pressure.
- Subject's desire to stop.
- Sustained ventricular tachycardia.
- ST elevation ($\geq$1.0 mm) in leads without diagnostic Q-waves (other than V1 or aVR).

Relative Indications

- Drop in systolic blood pressure of > 10 mm Hg from baseline blood pressure despite an increase in workload, in the absence of other evidence of ischemia.
- ST or QRS changes such as excessive ST depression (> 2 mm horizontal or down sloping ST-depression) or marked axis shift.
- Arrhythmia's other than sustained ventricular tachycardia, including multifocal PVC's, triplets of PVC's, supraventricular tachycardia, heart block, or bradyarrhythmias.
- Fatigue, shortness of breath, wheezing, leg cramps, or claudication.
- Development of bundle–branch block or intraventricular conduction delay that cannot be distinguished from ventricular tachycardia.
- Increasing chest pain

- Hypertensive response

*ACSM. ***ACSM's Guidelines for Exercise Testing and Prescription***, 6th edition, Philadelphia: Lippincott, Williams & Wilkins, 2000. (Box 5-3, p 104)+
Systolic blood pressure of more than 250 mm Hg and/or a diastolic blood pressure of more than 115 mm Hg.

APPENDIX C

SAMPLE Participant Instructions

Name of Participant:

_____

You have been scheduled for a Fitness Test with the LIFE Study. These instructions will help you in preparation for this test. You should allow enough time so that you can report to the testing laboratory approximately 15 minutes prior to the testing time listed below. If for any reason you cannot make the scheduled day and time, please inform the contact person listed below as soon as you are aware of a conflict.

****

Specifics:

Time of Test: _____ am. / p.m. Date of Test

_____/_____/_____

Location of Test:

_____

_____

Telephone: ( ) _____

Contact Person: _____

****

Purpose of the Fitness Test

The purpose of this test is to determine the how your exercise capacity changes during the study period. The test will require you to pedal on a stationary bike near maximal effort and therefore it is important to follow the instructions below.

Instructions Prior to Test:

- You should not eat any meals for **2 hours** prior to testing; however, a small (≤8oz) water, juice, or non-caffeinated soda is permitted. Beverages containing caffeine should be avoided.

- Come to the test with shorts (or loose slacks), comfortable walking or running shoes (these must tie or Velcro securely), loose T-shirt, towel/change of clothes (if not returning home after the test)
- If you are taking insulin/sulphonylurea, you may want to discuss with your physician if there is a need to reduce your dose the day of testing. This will depend upon your medication regimen and the time that testing is scheduled.

Questions?

If you have any questions regarding this test, do not hesitate to call the **Contact Person** at the phone number listed above.

Appendix D

BOX 2-2. Initial ACSM Risk Stratification

Low risk

Younger individuals* who are asymptomatic and meet no more than one risk factor threshold from Table 2-1

Moderate risk

Older individuals (men ≥ 45 years of age; women ≥ 55 years of age) or those who meet the threshold for two or more risk factors from Table 2-1

High risk

Individuals with one or more signs/symptoms listed in Box 2-1 or know cardiovascular,† pulmonary,‡ or metabolic§ disease

* Men < 45 years of age; women < 55 years of age.

† Cardiac, peripheral vascular or cerebrovascular disease.

‡ Chronic obstructive pulmonary disease, asthma, interstitial lung disease, or cystic fibrosis (see reference 12).

§ Diabetes mellitus (types 1 and 2), Thyroid disorders, renal or liver disease

Box 2-1. Major Signs or Symptoms Suggestive of Cardiovascular and Pulmonary Disease*

- Pain, discomfort (or other anginal equivalent) in the chest, neck, jaw, arms, or other areas that may be due to ischemia
- Shortness of breath at rest or with mild exertion
- Dizziness or syncope
- Orthopnea or paroxysmal nocturnal dyspnea
- Ankle edema
- Palpitations or tachycardia
- Intermittent claudication
- Known heart murmur
- Unusual fatigue or shortness of breath with usual activities

* These symptoms must be interpreted in the clinical context in which they appear because they are not all specific for cardiovascular, pulmonary, or metabolic disease.

For clarification and discussion of the clinical significance of the signs or symptoms, see reference 11.

Table 2-2 ACSM Recommendations for (A) Current Medical Examination* and Exercise Testing Prior to Participation and (B) Physician Supervision of Exercise Tests

	Low risk	Moderate Risk	High Risk
A.			
Moderate exercise †	Not Necessary ‡	Not Necessary	
	Recommended		
Vigorous exercise §	Not Necessary	Recommended	
	Recommended		
B.			
Submaximal test	Not Necessary	Not Necessary	
	Recommended		
Maximal test	Not Necessary	Recommended ‖	
	Recommended		

* Within the past year (see reference 2).

† Absolute moderate exercise is defined as activities that are approximately 3-6 METs or the equivalent of brisk walking at 3 to 4 mph for most healthy adults (13). Nevertheless, a pace of 3 to 4 mph might be considered to be “hard” by some sedentary, older persons. Moderate exercise may alternatively be defined as an intensity well within the individual’s capacity, one which can be comfortably sustained for a prolonged period of time (~45 min), which has a gradual initiation and progression, and is generally noncompetitive. If an individual’s exercise capacity is known, relative moderate exercise may be defined by the range 40-60% maximal oxygen uptake.

‡ The designation of “Not necessary” reflects the notion that a medical examination, exercise test, and physician supervision of exercise testing would not be essential in the preparticipation screening; however, they should not be viewed as inappropriate.

§ Vigorous exercise is defined as activities of > 6 METs. Vigorous exercise may

alternatively be defined as exercise intense enough to represent a substantial cardiorespiratory challenge. If an individual's exercise capacity is know, vigorous exercise may be defined as an intensity of >60% maximal oxygen uptake.

When physician supervision of exercise testing is "Recommended", the physician should be in close proximity and readily available should there be an emergent need.

Appendix E

Heart Rate Guideline Chart for Maximal and Submaximal Graded Exercise Testing

Age	Age-Predicted Maximal Heart Rate*	85% of Age Predicted Maximal Heart Rate**	80% of Age-Predicted Maximal Heart Rate***	70% of Age-Predicted Maximal Heart Rate****
45	175	149	140	123
46	174	148	139	122
47	173	147	138	121
48	172	146	138	120
49	171	145	137	120
50	170	145	136	119
51	169	144	135	118
52	168	143	134	118
53	167	142	134	117
54	166	141	133	116

55	165	140	132	116
56	164	139	131	115
57	163	139	130	114
58	162	138	130	113
59	161	137	129	113
60	160	136	128	112
61	159	135	127	111
62	158	134	126	111
63	157	133	126	110
64	156	133	125	109
65	155	132	124	109
66	154	131	123	108
67	153	130	122	107
68	152	129	122	106
69	151	128	121	106
70	150	128	120	105
71	149	127	119	104
72	148	126	118	104
73	147	125	118	103
74	146	124	117	102
75	145	123	116	102

* Represents the HR goal for the baseline GXT (patients not on a beta blocker).

** Represents the minimal HR that subjects (not on a beta blocker) must achieve on the baseline GXT.

*** Represents the termination HR for the submaximal GXT (patients not on a beta blocker).

**** If this 70% max heart rate value is exceeded within the first minute of the baseline GXT, the test must be stopped and restarted at a slower speed for subjects not on a beta blocker. (Note: For subjects on a beta blocker, if the RPE exceeds 13 in the first minute of the baseline GXT, the test must be stopped and restarted at a slower speed.)

APPENDIX F

Dear Dr. _____

Your participant, _____, has volunteered to be a participant in the LIFE Study. As a part of our cardiovascular screening for exercise participation, an exercise test was performed. This test revealed the following abnormal result:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

In order to participate in our program, we have recommended that your participant see you for evaluation of these findings, and receive approval from you prior to continuation.

Sincerely,

Principal Investigator, The LIFE Study

The LIFE Study participant, _____, was evaluated on _____.

The following evaluations/interventions were performed:

_____

_____

_____

S/He can ☐ cannot ☐ participate in the LIFE Study l

_____

Signature

APPENDIX G

Dear Dr. _____

Your participant, _____, is a participant in the The LIFE Study. Recently, s/he has reported the following symptoms:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

In order to participate in our program, we have recommended that your participant see you for evaluation of these findings, and receive approval from you prior to continuation.

Sincerely,

Principal Investigator, The LIFE Study

The LIFE Study participant, _____, was evaluated on _____.

The following evaluations/interventions were performed:

_____

_____

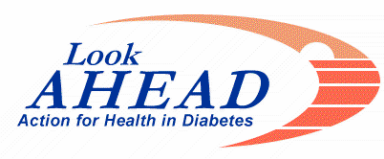
_____

S/He can ☐ cannot ☐ participate in the Look AHEAD Trial

_____

Signature

APPENDIX H



Date:

Dear Dr. _____

Your patient, _____, has been a participant in the The LIFE Study for _____ months. As a part of the study's follow-up, a graded exercise test was performed on the bike and compared to the patient's maximal graded exercise test completed at baseline. The exercise test just completed revealed the following abnormal result:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Based on these results we have recommended that your patient suspend any exercise that they do and to see you for evaluation of these findings. Please provide guidance related to your patient's ability to safely continue in the LIFE Study and to engage in an exercise program that is of moderate intensity. Once the patient has been evaluated please complete the bottom portion of this letter and fax to the attention of _____ at _____.

Sincerely,

(Principal Investigator, The LIFE Study) (The LIFE Study Study Physician)

The LIFE Study participant, _____, was evaluated on _____. The following evaluations/interventions were performed:

Physician Signature: _____

Appendix I

The Life Study - Graded Exercise Testing Review

Baseline Maximal Exercise Test

Test Date: _____ Subject PID: _____ Tech Name/ID _____

Evaluation Topic	**Technician Check** √	**Project Coordinator Check** √
1. Subject ID, date of test, visit code, and initials of reviewer provided.		
2. Gender and Age of Subject provided.		
3. Evaluation of resting ECG (only 1 box checked).		
4. Evaluation of contra-indications to testing.		
5. Course of action section completed (only 1 box checked).		
6. Cardiac Medications listed. (Indicate "none" when no medications are being taken).		
7. Hours since last food section completed.		
8. Pre-test blood pressures meet criteria.		
9. Pre-test heart rate recorded and is taken from resting ECG.		
10. Age-predicted maximal heart rate appropriately computed. * See attached heart rate chart. *Age-Predicted Maximal Heart Rate = (220 – age).		
11. 85% of age predicted maximal heart rate appropriately computed. *See attached heart rate chart. *85% Age-Predicted Maximal Heart Rate = [(220 – age) X 0.85].		
13. MET values for each GXT stage are completed and correct. *MET values based on chart provided.		
14. HR values for each GXT stage are completed.		
15. RPE values for each GXT stage are completed.		

16. Blood pressure for each even minute of the GXT are completed.		
17. Reason for termination listed on Page 2.		
18. Total exercise time, HRmax, and RPE max provided on Page		
19. HR and blood pressure recorded in recovery period.		
20. "Validity of Graded Exercise Test" section appropriately completed.		
21. Questions 1-11 on page 4 completed appropriately.		
21. Signature of attending physician included.		
22. Technician and Physician ID included.		