CHAPTER 3

Eligibility

Study Documents Referred to in this Chapter

- Short Physical Performance Battery
- Mini Mental Status Exam
- Behavioral Run-in

CHAPTER 3

ELIGIBILITY

3.1. OVERVIEW

Most of the older population is non-disabled and an important goal in this segment of the population is to prevent or postpone the onset of disability. However, there is a great deal of variability in the functional abilities within the population of non-disabled adults. Some older non-disabled persons are already very active and vigorous while others are sedentary and may actually have impairments and functional limitations that indicate an elevated risk of disability. The eligibility criteria in this study are aimed at identifying persons who are sedentary, have functional limitations as assessed by a battery of physical performance tests but who have not yet developed disability, as documented by their ability to walk 400 meters without the use of an assistive device. Targeting this subset of the population makes it possible to recruit a non-disabled but at-high-risk population for a clinical trial of disability prevention. This is a large segment of the older population in which the successful prevention of disability onset would have a major public health impact.

The goal of the eligibility inclusion and exclusion criteria are to identify participants who are at moderate or high risk for occurrence for developing walking disability, who are likely to adhere to the intervention, for whom the intervention is safe, and who are likely to benefit from a physical activity program. The following section describes the rationale used to select the eligibility criteria for this trial. This section of the MOP is provided as background for LIFE staff so that they can respond to questions that may be asked by a potential participant. The MOP chapter on Screening (Chapter 6) provides the detailed information about how to operationalize these eligibility criteria.

3.2. STUDY POPULATION

LIFE will recruit 400 participants at 4 clinical centers. The goal is for each of the centers to have an equal share in recruitment (100 participants from each clinical center). Participants will be recruited over nine months beginning in April 2004 and continuing through December 31, 2004.

3.3. INCLUSION CRITERIA

3.3.1 Elevated Risk for the Development of Walking Disability

The primary tool for quantifying the future risk of walking disability among older adults is the Short Physical Performance Battery (SPPB) developed by Dr. Jack Guralnik at the NIA. This battery is described in detail in Chapter 16. Briefly, the battery consists of three tests involving assessments of standing balance, walking speed, and the time to rise from a chair 5 times. The performance on these three tests is summarized into a single SPPB score that ranges from 0 – 12. The scores between10-12 represent good physical performance, and persons scoring in this range are unlikely to develop walking disability over the subsequent year or two. Therefore, entry in the study is restricted to participants who score from 0-9 on the SPPB.

3.3.2. Age

Individuals aged 70-85 years old are eligible. This age-group is selected because it is at high risk of major mobility disability, and has a sufficiently long life expectancy to participate in a full-scale trial which would have a duration of 3 to 4 years.

3.3.3. Gender/Ethnicity

Men and women are eligible. The LIFE Study endeavors to recruit men and

women in rough proportion to their representation in the catchment area population. All ethnic groups are eligible for the study. The LIFE Study goal is for a study cohort that is at least 25% from minority populations (primarily African Americans and Hispanic Americans).

3.3.4. Residency

Because the interventions require consistent participation in order to achieve the anticipated benefits, enrollees must be planning to reside in the clinic vicinity during the year following randomization. Also, because the study activities require frequent visits to the clinical sites, each clinic should define a catchment area as a target for recruitment. People living outside this area would be unlikely to participate because of transportation problems.

3.3.5. Walking Ability

The goal of the LIFE Study is to test an intervention to prevent walking disability defined as the inability to walk 400 meters without an assistive device in under 15 minutes. Therefore, participants who are already walking disabled cannot be enrolled in the trial. Walking ability is assessed twice. First on the telephone screen participants are asked: “Are you able to walk a ¼ mile, which is about 3 to 4 blocks, on a flat surface without the help of another person?”; and “Do you usually use a walker to get around the home?” Those answering “No” to the first question or “Yes” to the second are very likely disabled and will not be included in the study. During the first screening visit all participants will be asked to walk 400 meters (about a ¼ mile; 0.2485 miles). Participants who can walk the 400 meters in under 15 minutes without using a cane or other assistive device and without sitting down or stopping for more than one minute at a time will be eligible for the study.

3.3.6. Cognitive Function

Participants need to have sufficient cognitive abilities to both participate in the study interventions and to provide informed consent to the study. Cognitive

function will be measured using the Mini Mental Status Exam. Participants scoring below a 21 on this 30 point test will not be eligible for the study.

3.3.7. Physical Activity

One of the study interventions is a moderate physical activity program. Because this intervention is unlikely to be of any additional benefit to older adults who are already physically active, only sedentary adults will be eligible for enrollment in the study. Sedentary status is defined as having spent less than 20 minutes a week getting regular exercise over the previous month.

3.3.8. Chronic Disease Status

Chronic diseases are very common in the age group targeted by the LIFE study. In addition, poorer performance on the SPPB is also associated with the presence of chronic disease. The LIFE study is intended to provide evidence for recommendations to the general elderly population, so it is appropriate that participants with chronic disease be included in the study. However, those with certain severe conditions should not participate in the study because of their inability to participate in both intervention groups. These individuals will be excluded from the study.

3.3.9. Willingness to Participate

To be eligible, individuals must be willing to be randomized to either arm of the study. Individuals who only want to participate in the LIFE study if they can pick the group they are in should not be enrolled.

3.3.10. Behavioral Run-in

Participation in LIFE requires a high level of commitment from the study participants as well as the adoption of self-monitoring behaviors. Participants with

low enthusiasm are less likely to participate fully in the interventions and more likely to drop-out. Participants who are unable to track their own behaviors may have difficulty adopting the study intervention. To assess participants' willingness and ability to participate in certain aspects of the study they will be asked to record on a paper log daily information about the number and type of fruits and vegetables eaten and type and frequency of physical activity daily for one week between the first and second screening visits. At the second screening visit the logs are reviewed by a trained interviewer. To pass the run-in, participants must have written entries for at least 6 of the 7 days for both fruits/vegetables and physical activity. The quality of their responses is not rated. The Run-in is not used to determine the physical activity exclusion. The person conducting the review of the run-in can also make a decision not to pass the participant based on clinical judgment. Successful completion of self-monitoring is required for eligibility.

3.4. EXCLUSION CRITERIA

3.4.1. Exclusions That May Limit Adherence to Intervention or Affect the Conduct of the Trial

Since participants will be randomized to groups that require persistent on-going effort those who do not appear to be able to perform these activities will be excluded. Specific exclusion criteria related to the ability to fully participate are described below.

3.4.1.1. Unable or unwilling to give informed consent or communicate with local study staff

If participant cannot communicate with staff, they are unable to truly provide informed consent.

3.4.1.2. Current diagnosis of schizophrenia and other psychotic disorders Such illnesses may limit the individual's ability to adhere to the physical activity intervention and may increase the risk of behavioral difficulties, which could cause disruption to the group. Depression, per se, is not an exclusion. However, severely depressed individuals may find the requirements of the intervention overwhelming and may need professional, medical attention.

3.4.1.3. Current consumption of more than 14 alcoholic drinks per week (beer, wine, liquor)

Individuals with heavy alcohol consumption may be less likely to adhere and may be difficult to retain in the trial. Long-term participation in Alcoholics Anonymous is not an exclusion.

3.4.1.4. Plans to relocate to an area not served by a LIFE clinic or travel plans that do not permit full participation in the study

Such individuals would be unable to fully participate in the interventions and likely be lost to follow-up.

3.4.1.5. Failure to complete the two-week run-in for dietary intake and exercise See Chapter 6 and above. The run-in models the type of tasks that participants in the lifestyle intervention will be asked to complete. If an individual is unable to do these tasks for two weeks, it is unlikely that they will adhere to the same tasks during the study.

3.4.1.6. Another member of the household is a participant or staff member in LIFE

Only one member per household (excluding group living arrangements such as assisted living facilities), may be randomized. Participation is limited to one

person per household since behavior changes in one member of the house might likely affect others in the house. Other family members may be invited to attend educational sessions offered in LIFE.

3.4.1.7. Temporary Exclusion: Participation in another research study

Participants who are participating in another clinical trial at the beginning of the LIFE study should not be enrolled until they have completed their participation in the other study. There are two reasons for this exclusion. First, the interventions of LIFE and the other trial might conflict with one another. Second, the participant demand in the LIFE study is quite high, and participants may not be able to manage being in both studies at once.

3.4.1.8. Temporary Exclusion: Undergoing Physical Therapy

Activities done as a part of physical therapy may interfere with the participation in the physical activity group. Therefore, prospective participants who are undergoing physical therapy are not eligible for enrollment until the course of physical therapy has been completed.

3.4.2 Medical Exclusion Criteria for Underlying Diseases Likely to Limit Lifespan and/or Affect the Safety of the Intervention

3.4.2.1. Permanent Medical Exclusions

Medical Exclusions can be either permanent or temporary exclusions. Permanent exclusions are for those conditions that are unlikely to resolve during the screening interval or those that represent such severe disease that participation in the study may be limited by the illness.

3.4.2.1.1. Severe Chronic Disease

Although chronic disease is quite common among older adults, it may be so severe as to limit either the participation in the trial or life expectancy. Participants with very severe disease will not be eligible to enroll in the LIFE Study. Examples of severe disease include: severe arthritis; lung disease requiring supplemental oxygen or oral steroid medication; Parkinson's disease or other serious neurological disorder, kidney disease requiring dialysis; severe congestive heart failure (NYHA Class II or IV); clinically significant aortic stenosis; a history of cardiac arrest, the use of a cardiac defibrillator or uncontrolled angina. Other conditions that may come to light during the medical history review and physical exam of participants may also serve to exclude participants if the study medical officer or the PI deems that the condition is severe enough to render participation unsafe or if the participant's prognosis if poor.

3.4.2.1.2. Cancer in the past 3 years

Though cancer is quite common among older adults, some types have a poor prognosis or may be prone to relapse. In addition, cancer treatments may interfere with study participation. The most common forms of skin cancer are basal cell carcinoma and squamous cell carcinoma. These cancers have an excellent prognosis. Participants reporting only these forms of cancer are eligible for LIFE. Participants reporting melanoma skin cancer are not eligible. Participants reporting a history of colon, rectal, prostate, uterine, breast, cervical, thyroid, or oral cancer may be eligible for the study. These cancers have a good prognosis if caught early in their natural history. Patients undergoing current radiation or chemotherapy for these cancers are not eligible for the LIFE study. Patients with a recent history of these 8 kinds of cancer but who are not currently receiving treatment may be eligible at the discretion of the clinical center's PI or the PI's designee. Participants reporting a recent diagnosis of cancer of any type other than the 10 listed above are not eligible for the LIFE Study.

3.4.2.1.3. Symptoms developing during the 400m Walk Test.

Participants developing substantial shortness of breath or chest pain during the 400m walk test are at high risk of experiencing an adverse event during the study and can not safely participate in the physical activity group. These participants are to be excluded from the LIFE study.

3.4.2.2 Temporary Medical Exclusions

3.4.2.2.1 Uncontrolled Hypertension

Physical activity may be unsafe in those with severe uncontrolled hypertension. If at Visit 1 a participant is found to have a systolic blood pressure greater than 200 mmHg or a diastolic blood pressure greater than 110 mmHg, the participant should be referred to their health care provider for treatment. Once treated, the participant will be eligible for the study.

3.4.2.2.2 Uncontrolled diabetes with recent weight loss, diabetic coma or frequent insulin reactions.

Study participation may be unsafe in those with uncontrolled diabetes. Participants with evidence of uncontrolled diabetes should be referred to their health care provider. Once the diabetes is brought under control the participant may be eligible for the study.

3.4.2.2.3 Stroke, hip fracture, hip or knee replacement, or spinal surgery in the past 6 months.

Individuals should not be enrolled in the study during the recuperative period following a stroke, hip fracture, joint replacement surgery or spinal surgery. Prospective participants are ineligible until 6 months has elapsed from the date of the event.

3.4.2.2.4 Serious conduction disorder (e.g., 3rd degree heart block), uncontrolled arrhythmia, or new Q waves or ST-segment depression (>3 mm) on ECG. Participants with any of these findings should be referred to the primary care physician. Participants can be re-evaluated after obtaining appropriate treatment.

3.4.2.2.5 Myocardial infarction, major heart surgery (i.e. valve replacement or bypass surgery), stroke, deep vein thrombosis or pulmonary embolus in the past 6 months.

Prospective participants experiencing the above mentioned events are at increased risk of recurrent events especially during the period immediately following the initial event. Therefore, participants will remain ineligible until 6 months has elapsed from the date of the event.

3.4.2.2.6 Other reasons for temporary exclusions

Many other unlisted or less common events or conditions may be considered for temporary exclusion based on the following decision making processes. In the case of any potential "other" exclusion, the site study physician may obtain additional medical information from medical records or from the potential participant's providers in accordance with all local requirements for release of medical information. If the site study physician feels that the condition places the prospective participant at serious increased risk from participation in the study, then he/she may recommend temporary exclusion for a period up to 6 months. The length of the temporary exclusion may be individualized. Alternatively, a study physician may request an opinion regarding safety of participation from the prospective participant's primary physician. The study physician may then incorporate the primary physician's opinion into a final recommendation about the need for and length of a temporary exclusion. Study physicians are encouraged

to bring these cases to the recruitment committee for discussion in order to improve consistency across sites.