CHAPTER 25

INTERVIEWING

Study Documents Referred to in this Chapter:

- Telephone Screening Interview
- Contact Information
- Demographics
- Disability Questionnaire
- Process Measures
- MMSE Exam
- Medication Inventory
- Medical, Hospital Admission History
- Quality Well Being
- Health Care Utilization
- CHAMPS Battery
- HRQL
- Late Life Disability Questionnaire
- 400m Walk Proxy
- Updated Contact Information
- Cognitive Tests (WFU and Stanford only)
- Health Events

CHAPTER 25

INTERVIEWING

25.1. STANDARDIZED INTERVIEWING PROCEDURES

Consistency and standardization in procedures is critical for good data collection. All interviewers in the LIFE study should follow standard procedures in reading questions and recording participant information. Each question must be asked of each participant in the same way and in the same order to ensure that comparable information is being obtained from all participants in the study. The data collection forms contain specific instructions and scripts that should be followed precisely.

It is essential that interviewer's present questions appropriately, record participants' replies precisely and accurately, and probe for additional information meaningfully. To maintain an objective information-gathering atmosphere, the interviewer must convey that he/she is an understanding, interested person capable of accepting information in a non-judgmental manner. When talking to a receptive, supportive interviewer, participants will feel more comfortable without fear of appearing inadequate.

Previous studies have identified several factors that increase the respondents' receptiveness:

- Be prepared and know your material. Participants need to feel that you are interested in the study and in their opinions. Be an active listener and establish comfortable eye contact with the participant.
- Offer convincing statements about the purpose of the study.
- Describe the beneficial uses of the research findings to both the respondent and to the community.

There are two main types of questions, closed-ended and open-ended. With closed-ended questions, the interviewer will check the appropriate box. With open-ended questions, the interviewer will record the participant's answer word-for-word by writing it in the space provided. Open-ended questions do not suggest possible answers; the participant's responses should be recorded in his/her own words.

Questions:

- Read slowly in a natural conversational rhythm and in a normal tone of voice.
- Always read the entire question before getting the participant's response.
- Be aware of the participant's facial expressions, e.g., puzzled, confused.
- Repeat the question if it is answered inappropriately, but repeat it exactly as written.
- Offer to reread a question if you believe the participant did not understand what was asked.
- Ask questionnaire items in order and exactly as worded.
- Unless the instructions indicate otherwise, ask every question. Often a previous statement by the participant will partially answer another question, but rarely does it answer that question completely. Do not omit any questionnaire items.

Responses:

- LEARN THE PURPOSE OF EACH QUESTIONNAIRE ITEM. You need to understand the information we are trying to obtain through each question. Unless you understand its purpose, you will not be able to judge when a response is adequate.
- DON'T ATTEMPT TO INTERPRET/EXPLAIN THE QUESTION—MAINTAIN NEUTRALITY. If a participant does not seem to understand a question, repeat the

question slowly and clearly. Unless you have other instructions about handling specific questions, the acceptable reply for a participant who wants to know what a question means is, "Whatever it means to you." Do not attempt to explain the purpose of a question unless the interviewer instructions specifically authorize you to do so.

- DON'T DEFINE TERMS USED IN QUESTIONS UNLESS THE STANDARD DEFINITION IS INCLUDED FOR THE QUESTION. Some participants may ask, "What is meant by a word used in a question?" Leave the matter of definition to the participant. For example, you might respond, "Whatever you think it means" or "However you use the term."
- DON'T LEAVE A QUESTIONNAIRE ITEM UNTIL YOU HAVE AN ADEQUATE RESPONSE OR HAVE DETERMINED THAT A PARTICIPANT CAN'T GIVE A CLEARER RESPONSE.
- PARTICIPANTS MAY REFUSE TO ANSWER ANY QUESTION. However, refusal to answer some questions, such as those determining study eligibility, can affect whether or not a person may participate in LIFE.

Probing:

- SILENCE. The value of silence cannot be overestimated. The interviewer who can wait quietly and patiently will soon find that 15 seconds of silence will often allow a participant to expand or clarify a previously inadequate response.
- REPEATING THE QUESTION OR RESPONSE CATEGORIES. Be sure to repeat the question as stated in the questionnaire. This is particularly useful when the participant provides an inappropriate response. In some cases it is necessary to remind the participant of your frame of reference, i.e., to acknowledge what the participant has said and then bring the participant back to the topic by repeating the question.
- DO NOT ACCEPT A "DON'T KNOW" RESPONSE OR A REFUSAL WITHOUT PROBING AT LEAST ONCE. If a response is "don't know," probe by asking, "Well, what

do you think?" If the question deals with facts, an approximation is preferable to no answer at all. The interviewer might probe, "What's your best guess or approximation?" to convey the idea that 100% accuracy is not required. If the participant persists with "don't know," do not harass him/her; accept that as him/her answer. A made-up answer to please the interviewer is no better than a "don't know." If a participant refuses to answer a question, you might remind them that their answers are completely private and confidential, and will not be revealed to anyone without their consent.

- USE NEUTRAL PROBES THAT DO NOT SUGGEST ANSWERS. Probes are needed to obtain more complete, accurate answers. All probes must be nondirective, i.e., the probe must not suggest any particular answer to the participant. Probes should be used whenever the participant is hesitant in answering questions, whenever the participant seems to have trouble expressing himself/herself, whenever the participant seems too shy to speak at length, and whenever there is any reason to believe that the participant has not given a complete report of his/her thoughts. Finally, reassuring probes are needed when a participant seems to lack confidence.

- EXAMPLES OF OTHER NEUTRAL PROBES:
  - "Could you tell me in what way?"
  - "Can you give me an example?" or "For example?"
  - "Can you explain that in a little more detail?"
  - "I am wondering how you are using the term . . .?"
  - "If you had to choose, which would you say?"
  - "In general, overall . . .?"
- ALWAYS CROSS-REFERENCE. When you probe to clarify a response, always indicate which response you are clarifying. There will be times when a participant will say something ambiguous and continue talking.

- DON'T ASK, "Do you mean . . .?" People tend to say "yes" to any suggestion, either because it is easy or because they think it is the right answer.

- MAKE PROBES CONSISTENT WITH THE PURPOSE OF THE QUESTION. Any probe that does not suggest answers and that is non-threatening is acceptable provided it is appropriate to the particular interviewing problem.
- WATCH FOR VAGUE, INCOMPLETE ANSWERS. A probe such as, "Tell me more about . . .", is effective.
    - Do not accept qualified answers or "depends". When the participant gives a response of this nature, it is advisable to use probes such as repeating the question or prefacing the question with a phrase such as, "Well, in general . . ."

25.1.1. Appearance and Demeanor

Clean, neat, professional dressing and style are important. The interviewer's dress and demeanor should convey that he or she is an appropriate representative of the medical community, that the research is important, and that the participant is a respected member of the study.

The demeanor of the interviewer should be casual, yet professional. This is a difficult balance to maintain and requires a thorough familiarity with the questionnaires and procedures prior to interviewing the first participant. Although it is essential that the structured interview be followed verbatim, the interviewer should not sound like a recording. The interviewer should know the questions so well that it never sounds as if he or she is reading them formally. The interviewer should use a natural, conversational style. At the same time, the interviewer needs to "stay on track" and politely, but firmly, lead the participant through the interview.

Finally, the interviewer should be pleasant and friendly. As noted by Backstrom and Hursh-Cesar (1981), “A major objective is to put the respondent at ease. If the participant isn’t relaxed, [the interviewer] can’t make the participant talk.” Similarly, “the burden of ignorance has to be lifted from the respondent’s shoulders—that is, he or she must not be made to feel ashamed of his/her lack of information. [The interviewer’s] attitude, therefore, must be sympathetic and understanding. Emphasize that there are no correct answers. Rather, [the participant] must realize that what he or she thinks really is what counts. An opinion can never be wrong.”

25.1.2. Privacy and Confidentiality

It is critical that each interview be conducted in a quiet, private area within the clinical center. Each clinic should have a designated area that is comfortable for the participant and free from intrusions.

Similarly, it is important that the participant be the only respondent during the interview. The spouse/partner, friends, or relatives should not be present during the interview, because their presence will influence the participant’s responses to questions. If someone is with the participant and is reluctant to leave, explain the necessity of privacy for study purposes and be prepared to suggest places where this individual can wait comfortably. You might say, This will take about 15 minutes; the coffee shop is located down the hall”, etc.

Participants must be assured of confidentiality and it is critical that confidentiality be maintained throughout the study. As noted by Westat (1987): “An interviewer must often ask questions that one would not think of asking even a close friend. Most people, however, are willing to answer such questions when they are asked in an interview. They are willing to give information because they trust that it will be used only for serious purposes.” Your protection of all information about

participants gained during the conduct of research is therefore essential. This means to protect not only the information you get in direct response to the questions you ask in an interview, but also the information you gather through incidental observations of the participant.

It is also important that care be taken in maintaining confidentiality of completed questionnaires while they are in your possession. Always make sure that questionnaires are not left where non-research staff can view them. You must safeguard the completed questionnaires by not leaving them unattended, such as in your car where they might be stolen, or in a school room, clinic room or office where anyone could walk in and read them.

It is your duty to keep the promise of confidentiality. Never divulge names or tell facts about or reveal the opinions of anyone you interview.

Information collected or seen during an interview can be shared only with the research team, whose members are under the same ethical or moral obligation as you are to the participants interviewed. As you may know, persons who participate in research studies have rights to privacy that are protected by federal law. Maintaining confidentiality of data is not just a philosophical issue for an interviewer. It means that an interviewer must be aware of the importance of protecting the confidences of the study participants on a day-to-day basis. For example, an interviewer's comment to a friend outside of the research team about a particular participant or about a participant's response is a breach of confidentiality and is considered unprofessional conduct.

25.1.3. Preparation for Interview

The interviewer should:

1. Review the Manual of Procedures and training materials.
2. Go through the structured interview carefully.
3. Organize all the necessary materials, including pencils, extra paper, a clipboard, etc.
4. Be certain the interview room is neat and organized.
5. Review the information available on the participant and information needed for the interview (e.g., time of appointment, name of participant, etc.)
6. Be certain his/her appearance is appropriate for the interview.
7. Obtain the necessary response cards, which are numbered sequentially.

25.1.4. Response Cards

For some questions/instruments, the interviewer is instructed to show the participant a response card, which will include the possible response categories for the relevant question(s). These cards are numbered sequentially and should facilitate ascertainment of accurate responses and minimize the need to repeat the response categories.

25.1.5. Respondent Questions

The interviewer should be familiar with all questions and their meaning. In response to requests for clarification, reread the question exactly as it appears, stressing by your voice intonation references to time, place, and question intent – for facts or feelings. Stem questions should be repeated periodically as needed. Do not ad-lib an explanation of the question. It is critically important to stay with

the literal expression of the questions since this is the best way to ensure that data collected at the many clinical sites are comparable.

25.1.6. Respondent Complaints

Always empathize with the participant who has a complaint about the questionnaires (or other clinic activities). Give them the courtesy of listening to their complaint. For instance, if the participant complains of particular wording or redundancy or length of the questionnaire, say, you don't know why it was done as it was, but it is important for the participant to answer as best they can. Indicate that some of our forms are standardized forms and because of that they may seem redundant. In any case, it is important for them to do the best they can.

25.1.7 Administration of Instruments to Hispanic/Latino Participants

Bilingual staff is requested to ask new volunteers what their language of preference is (English or Spanish) and administer questionnaires in the language they specify. Existing participants will be prompted to continue with the questionnaires in Spanish if they so desire.

1. Familiarize yourself with the script so that you read it accurately and clearly.
2. Weight and length/distance measures are provided in decimal units (meters, kilograms) in the questionnaires for participants who are more familiar with the decimal system.
3. Bear in mind that some Hispanic/Latino participants may have seasonal or temporary jobs and receive weekly wages. Thus, they may find it difficult to ascertain their annual income. If that is the case, multiply their weekly wages times 52 to obtain the annual amount earned.

For example:
In the Demographics questionnaire, question 14, on salary information.

14. Aproximadamente, ¿qué ingreso se recibió en su casa de toda fuente el año pasado sin los descuentos por impuestos (incluyendo sueldos, jubilaciones, inversiones, etc.)? *(Show response card demg 1)*

A. Menos de $5.000	☐	F. $35.000 a $49.000	☐
B. $5.000 a $9.999	☐	G. $50.000 a $74.999	
C. $10.000 a $14.999	☐	H. $75.000 o más	☐
D. $15.000 a $24.999	☐	I No sé/Se negó a contestar	☐
E. $25.000 a $34.999	☐		

4. Due to low literacy level among many Hispanic individuals, it may be necessary to read Informed Consents to them. ☐
5. Medication Inventory: You may want to encourage participants to inform of any home remedy they may have been using or taking.

25.2. SELF-ADMINISTERED QUESTIONNAIRES

This method of administering questionnaires for data collection is used sparingly in the LIFE study, i.e. only for the cost-effectiveness measures. As with the interviewer-administered questionnaires, it is critical that the self-administered questionnaires be handled in a standardized manner.

25.2.1. Mailed Questionnaires

Participants are asked to complete the Quality of Well-Being and Health Care Utilization questionnaires at home and bring them to the second pre-randomization screening visit and 6- and 12-month follow-up clinic visits. The questionnaires are provided to participants after the first pre-randomization screening visit and are mailed to participants prior to the follow-up clinic visits. Responses to questions in self-administered interviews will often be incomplete, missing or inappropriate. The questionnaires should be reviewed carefully the day they are received in the clinic before participants leave the clinic so that

discrepancies can be resolved immediately. Specific items to check are covered in the sections under each questionnaire, but in general check for:

- Unanswered questions or blank spaces.
- More than one answer marked if directions indicate “check only one.”
- Incorrect skip pattern responses.
- Participant attempting to change the wording of the question and answering it according to the “new wording.” For example, if the question asks, “How often do you drink regular soda pop?” and the participant crosses out the word “regular” and writes in “diet.”

Changes on questionnaires made by study staff should be made in a different color pen than that used by the participant; these changes should be initialed and dated. Do not erase any marks made by participants. Rather, draw a line through any marks to be ignored by data entry.

All questionnaires, interviewer-administered and self-administered, should be rechecked an additional time by a second data collector/interviewer before submitting the questionnaire to data entry. Initials of the two staff persons checking the questionnaire should be used to verify that it is ready for data entry.

25.2.2. Literacy or Vision Difficulties

While the self-administered questionnaires are designed for ease of administration, for a variety of reasons you can anticipate that some participants will have difficulty completing the questionnaires by themselves. Approximately 6% of the American population (with a range from 2-14% across individual states) is formally considered functionally illiterate, having completed fewer than four years of schooling. This rate is probably a gross underestimate of the number of individuals who are likely to have difficulty completing a self-

administered questionnaire because of problems in concentration, reading fluency, or comprehension. In addition, some participants will have vision problems or difficulty in writing responses. Individuals with low literacy skills come from a variety of educational backgrounds and age levels. One of the stereotypical myths about illiteracy is that you can recognize an individual who is illiterate by their appearance. One must remember that an individual's comprehension skills are silent and invisible. Many individuals will have high intellectual skills in areas of visual memory and good verbal skills. To identify individuals who may have problems filling out forms, look at answers to questions on forms that may be inconsistent with what you know about the participant. Be aware that participants will try to conceal the fact that they cannot read well or understand; participants may use excuses such as, "I don't have my glasses;" "my eyes are tired, would you read this for me?" Another clue is when a participant says, "I want a family member/friend to look at these first."

While we cannot accurately estimate the number of participants in LIFE who will have literacy or vision difficulties, some participants are likely to have problems in these areas. It is important to provide these participants with the opportunity to have the questionnaires administered by the interviewer. When handing the questionnaire to the participant, the interviewer should say to the participant, "We have found that some people prefer to have the questions read to them. Would you like me to read these questions to you?" If the participant says no, the interviewer should indicate availability to answer any particular question, which may arise during completion of the questionnaire.

25.2.3. Confidentiality and Comfort

As with other interviews, it is important to indicate to the participant that his/her responses to self-administered questionnaire are confidential.

When required, assist the participant in finding a comfortable, quiet place to complete the questionnaire. If this place is not in the immediate clinic area, it is important that you take responsibility in making sure that the participant is returned to familiar surroundings once the questionnaire is completed. Be sure that the room is tidy and ready and that any needed supplies, such as pens and forms, are available.

We ask that the participant complete the questionnaire without the help of a spouse or friend, and you should discourage others from staying with the participant while he/she is completing the questionnaire. Although this may not always be possible, you should reinforce the value of the participant's own responses.

Emphasize again that you are available to answer any questions that may arise.

25.3. SCHEDULE OF ADMINISTRATION

The schedule of administration of the interview forms is shown in Table 25.1 on the following page.

Table 25.1. LIFE Interview Forms Schedule

Visit type	Scr	Scr	Rnd	Tel	Fu	Tel	Fu	Tel	Fu/Cls	End	Nsv
Visit Code		S01	S02	F03	F06	F09	F12	F15	F15/ F18		
Clinic or Home Visit number		1	2		3		4		5	6	
Telephone call	1			2		3		4			
Week number		-2	0		26		52		78	65-91	
Activity/assessment Month number		-0.5	0	3	6	9	12	15	15/18	18/21/24	
Form name											
Telephone Screening Interview	x										
Contact Information		x									
Demographics		x									
Disability Questionnaire		x		x	x	x	x	x	x	x	x
Process measures		x			x		x				
MMSE Exam		x									
Medication inventory		x			x		x				
Medical, hospital admission history		x									
Quality of well being (CEA)			x		x		x				
Health care utilization (CEA)			x		x		x				
Study Eligibility Checklist (Run-In Review)			x								
CHAMPS battery			x		x		x		x		
Late Life Disability Questionnaire			x		x		x				
400 M Walk Proxy					x		x				
Health Related Quality of Life (HRQL)			x		x		x				
Updated contact information					x		x		x		x
Cognitive Tests (WFU and Stanford only)			x				x				
Health Events				x	x	x	x	x	x	x	x
Scr=Screening visit; V=Visit; Rnd=Randomization; F=follow-up visit; Cls=Close out visit; Nsv=non-scheduled visit; End=Endpoint Visit											

25.4. TRAINING AND CERTIFICATION FOR LIFE CENTERS

After carrying out the questionnaire training, program coordinators (PCs) should conduct at least two sessions with each data collector/interviewer prior to having them collect data on real participants. The following format is suggested:

Volunteers: Use colleagues, clinic staff, or other nonparticipant volunteers.

Central Training at Clinics: Interview prospective age-eligible participants/volunteers. (See Certification form description Chapter 24.)

From Pre-randomization Screening Visit 1

1) Contact information
2) Demographic, social, economic
3) Medical and hospital admission history
4) MMSE screener

From the Follow-up Clinic Visits

1) 400 m walk questions
2) Safe care review and Late Life Disability Questionnaire
3) Health events
4) Health related quality of life measures
5) Cognition
6) Process measures, physical activity
7) Medications, Quality of well being, health care utilization

Corrective Actions: Should any problems related to bias, standardization, interviewing skills, or forms editing be apparent, the PC should work with the data collector/interviewer on these areas. Retaping with additional volunteers should then occur within a seven to ten day period.

The second set of tapes should be reviewed as soon as possible. If problems are still apparent, the PC should assess the appropriateness of using this staff member for data collection on LIFE.

Tip: Every data collector/interviewer must meet LIFE standards in order to be a part of the study.

Certification: Certification of each data collector/interviewer is complete when the training and audiotape practice has been completed to the satisfaction of the Program Coordinator.

Re-certification: Re-certification on standardized methods of administering the questionnaires should take place annually by the Program Coordinator. The process should be the audiotape procedure described under certification. Periodic checks might also be conducted by "sitting in on a random interview" (after asking permission from the participant) and/or by "double checking questionnaires for correct completion" before they are sent to data entry.

25.5. SPECIFIC QUESTIONNAIRE INSTRUCTIONS

25.5.1. Telephone Screening Interview

This questionnaire is administered to prospective participants either by phone or in person. It is used as the first screen to establish eligibility. The questions included are designed to 1) obtain basic demographic information about prospective participants, and 2) screen out prospective participants who are clearly ineligible. This interview should not be administered until the verbal consent script has been read and the prospective participant has agreed. LIFE Study ID's are not assigned until verbal consent has been obtained.
If a participant breaks off the interview, mark all remaining unasked questions "refused".

The answer boxes are color coded. Answers that lead to exclusions are shaded. Eligible participants will only have unshaded boxed marked.

Instructions

Page 1

Questions 1-4 collect contact information about the prospective participant. This information is crucial because instructions for the preparation for the first screening visit are sent to this address, and the phone number is used to remind participants of appointments. Check the accuracy of the address and phone number carefully.

Derive the Acrostic

Once the full name is collected, the interviewer is able to derive the acrostic for the participant. The Acrostic is a secondary identifier for the participant that is used as a cross-check. It is a 5-letter code made up of the first three letters of the participant's last name and the first two letters of the participant's first name. Instructions for deriving the acrostic are provided in Chapter 4.

Question 5 asks about where the participant heard about the study. This information is useful for tailoring recruitment strategies.

Page 2

Ask all participants all questions on this page, unless it is established that the participant either geographically or age ineligible...

Question 6 Determine if the zip-code of the prospective participant is in the target area for your clinical site. Participants will have to travel frequently to intervention sites, and if they live a long way from the site they are unlikely to be able to participate fully. The interview can be terminated once it is established that participant does meet the zip code criteria.

Question 7 Participants who say they "don't know" or refuse to answer are ineligible.

Question 8 Ask the participant his/her age. Record the given age on the form. If the age is outside of the target age-range of 70-85 the participant is ineligible and the interview can be terminated. Indicate if the participant's age is in the target age-range in the boxes. Participants who say they "don't know" or refuse to answer are ineligible.

Questions 9 – 10 are self-explanatory.

Question 11 The NIH requires that all studies involving humans report the gender and ethnic make-up annually. The NIH distinguishes between "ethnicity" and "race." Question 11 asks about Latino/Hispanic ethnicity. Participants may refuse to provide this information and still be eligible for the study.

Question 12 This question asks about race. Participants may refuse to provide this information and still be eligible for the study.

Question 13 refers specifically to using a walker in the home. The use of a cane does not count, and persons using canes may be eligible.

Question 14 You may want to determine what commonly recognized distance is ¼ of mile to cue participants who are unsure. Participants who refuse to answer are ineligible. Participants who say they "don't know" can be brought in for a screening visit to determine their ability to walk this distance.

Question 15 The time reference is the past month. A participant saying they used to exercise until they got sick two months ago would be eligible. The additional questions are for the purpose of probing the participant to ascertain the type, frequency, and total amount of exercise.

Question 16 Interviewer note to calculate the total number of minutes per week spent exercising..

Question 17 If the participant is hard of hearing or cannot talk clearly or does not seem to understand the questions the interviewer should mark "YES," and the participant is ineligible.

Question 18 The Interviewer should check to see that only unshaded boxes have been checked on Questions 6-15 and 17; and that the total number of minutes of exercise per week is less than 20 minutes for Question 16.. If this is true, the interviewer should check "Yes" and go on to page 3. If any shaded boxes have been checked, the interviewer should check "No" and go on to page 3.

Page 3

Questions 19-28 Any answer of "Yes" on this page results in exclusion; however, pages 2-4 are completed on everyone. Because some older people can be poor medical historians, answers of "Don't Know" are acceptable answers and do not lead to exclusion. These responses can be follow-up by the study medical officer

during the first screening visit. If a participant refuses to answer any question on this page they are also ineligible.

Question 21 & 24 The interviewer may not recognize certain medical problems. If you are unsure write the participant's verbatim response in the space provided do not mark an answer for this question and continue with the interview. Check with the administrative center and your site PI to see if the condition warrants exclusion. Complete the questionnaire and follow-up with the participants appropriately.

Question 29 After completing Question 28 confirm the participant is still eligible (only unshaded boxes are checked) and proceed to Page 4.

Page 4

Question 30a – 30b.These questions ask about cancers or malignant tumors participants may have had. We are only interested in cancers diagnosed or treated in the three years before the interview. Participants with tumors diagnosed more than 3 years ago are eligible for the study.

Some people may have had more than one cancer diagnosed or treated in the past 3 years. Mark each box as appropriate. If a person has had two cancers one of which would have made the person ineligible (for example, leukemia) and on that would not (for example, squamous cell skin cancer) they are ineligible.

Participants with non-melanoma skin cancer are eligible for the study. This includes basal cell carcinoma and squamous cell carcinoma. If the person does not know what kind of cancer they might have had they should be considered eligible. The study physician will follow-up during the screening visit.

There are 8 common cancers that can have varying prognosis: breast, cervical, colon, prostate, rectal, uterine, thyroid, and oral cancer. Participants are eligible

if they have completed a course of treatment for these cancers. If they are currently receiving either radiation therapy or chemotherapy they are not eligible. Chemotherapy does not include certain drugs that are used to suppress cancer recurrence such tamoxifen. If you are unclear about the drug, mark the person as eligible, and have the study physician follow-up.

Any cancers other than the 10 mentioned above (basal cell carcinoma of the skin, squamous cell carcinoma of the skin, breast, cervical, colon, prostate, rectal, uterine, thyroid, and oral cancer) leads to an automatic exclusion. If a person is ineligible read the script at the bottom of the page and terminate the interview.

Question 31 Confirm the participant's eligibility based on pages 2-3 of the form. If the participant is eligible, go on to page 5. If the participant is ineligible terminate the interview by reading the script at the bottom of page 4.

Page 5

Questions 32-40 This page lists temporary exclusions. These are exclusions that may only apply for a short-while. It is up to the interviewer to determine whether participants are likely to become eligible during the recruitment period. If the participant might become eligible make plans to recontact the participant at the appropriate times. If not, terminate the interview.

Questions 32-38 refer to health events in the previous 6 months. If a participant answers yes determine how long ago the event occurred. If six months will have elapsed between the event and the end of the recruitment period, schedule a follow-up call for that time.

Question 39 - Refers to physical therapy. Participants are eligible once physical therapy has ended.

Question 40 - Refers to the participation in other trials. Participants should not be in two trials at the same time. Many studies, especially drug studies, can be of a relatively short duration. Participants are eligible for LIFE once they have completed other studies they may be in.

Question 41 – After completing Questions 31-39, if the participant is only temporarily ineligible, get permission to recontact him/her in 1-6 months.

Question 42 If a participant is eligible based on answers to the previous questions, schedule him/her for a clinic screening visit. The participant may want additional information about the study at this point, and you should be prepared to provide it. If a participant refuses participation at this point mark the reason for refusal on the form and terminate the interview.

25.5.2. Contact Information

Contact information should be obtained during the first pre-randomization screening visit.

Complete and accurate collection of contact information is essential for minimizing missing data and losses to follow-up. Contact information should be collected on the participant, a potential proxy, two other persons who know the participant well, and the participant's primary health care provider.

Whenever possible, ask to see the participant's social security and Medicare cards. Some persons may be hesitant to provide this information. Emphasize that all information collected for the study is strictly confidential and that identifying information is omitted from all study forms.

It is essential that complete information be obtained for at least one potential contact. The goal should be to collect information for a potential proxy respondent (Q6-6b) and two different contacts (Q7-7d). If the participant cannot recall the complete addresses and/or phone numbers, ask them to bring this information to the second pre-randomization screening visit.

The ideal proxy respondent lives with the participant. If the participant lives alone, identify the person who knows the participant best. Ideally, this person sees or talks to the participant at least three days a week.

If the participant cannot recall the complete contact information for their primary health care provider, ask them to bring this information to the second pre-randomization screening visit.

25.5.3. Update of Current Contact Information

The initial contact information form should be updated as indicated during the course of the study. During each clinic visit, the participant should be asked whether the currently identified proxy is still suitable. The ideal proxy respondent lives with the participant.

If the participant lives alone, the person who knows the participant best should be identified. Ideally, this person should see the participant at least three days or 10 hours a week. If the participant identifies an alternative proxy, this information should be indicated on the Update of Current Contact Information form and the Contact Information form should be updated accordingly.

25.5.4. Demographics

Demographics information should be obtained during the first pre-randomization screening visit. This information will allow us to accurately describe our study population and to determine whether certain subgroups of individuals are more or less likely to benefit from the study interventions.

For the Other response category for Q5 (education), write in the last school year/grade (beyond 16) completed in the space provided.

For Q13 (Occupation), do not read the response categories. Use the participant's response to identify the correct category.

For Q14 (Income), some participants may be reluctant to provide this information therefore response cards should be used for this question. Emphasize again that all information collected for the study is strictly confidential and that identifying information is omitted from all study forms.

25.5.5. Disability Questionnaire

The Disability Questionnaire should be completed during the first pre-randomization screening visit and subsequently during each of the follow-up telephone interviews and clinic visits.

The Disability Questionnaire assesses the participant's ability to complete an array of important day-to-day activities without difficulty and, for a subset of activities, without personal assistance. This information will allow us to determine whether the study interventions improve the ability to manage day-to-day activities.

For Q8-Q15, participants who have difficulty with the task, even they don't do for other reasons, should be asked whether they usually receive help from another person for the task.

For Q8-Q33, the interviewer should periodically repeat the stem. If the questionnaire is administered over the phone, repeat the response options periodically as well. For participants who respond that they were unable to do a task, verify that this was for health reasons. If the task was not done for health-

related reasons, mark an X in the box labeled, “Unable to do the activity”. If the task was not done for reasons not related to health, mark an X in the box labeled “Did not do for other reasons”.

25.5.6. Process Measures

The instrument used to evaluate the psychological and behavioral processes hypothesized to be affected by the LIFE intervention consists of a) Self-Efficacy for Walking; b) Self-efficacy for Barriers to Active Living; c) Satisfaction with Physical Function; d) Desire for Physical Competence; and e) a measure of self-regulatory-related traits. This instrument is interviewer-administered at the first screening visit (SV1; baseline), 6-months, and 12-months. All participants will complete this instrument in the clinic.

Please Note: It is important that this instrument be completed immediately following the 400 M Walk and should be administered if the walk was terminated early. It should also be administered even if the walk was not administered for safety reasons.

It is also important to note that the administration of these measures during follow up clinic assessments may be particularly vulnerable to unmasking. In other words, the potential is high for participants to inadvertently reveal their group assignment while responding to process measure items. For example, note that the instructions for the Self-efficacy for Barriers to Active Living measure include the script, “Some of the questions I am going to ask may sound strange, but I would like to remind you again, that for scientific reasons, please don’t tell me to which of the two LIFE groups you were assigned.” Administrators should be vigilant to prevent participants from revealing their group assignment.

These measures were created based on social cognitive theory and assess participants’ perceptions of their capabilities to perform various physical tasks and their satisfaction with and desire for physical functioning. Responses for each scale are averaged and are analyzed individually.

Be sure to read each item slowly, carefully, and exactly as written. Be sure to enunciate your words carefully and have patience with participants. Most of these questions will seem very unusual to them.

Self-efficacy for Walking

This scale assesses participants' confidence in their ability to walk incremental distances one week from now: 5 laps, 10 laps, 15 laps, and 20 laps. These distances were chosen because of their relationship with the assessment of the main study outcome: the 400 meter walk. Therefore, the instructions for this measure were written so as to give participants a frame of reference (in relation to the number of laps walked during the 400 meter walk) so that they may more precisely evaluate their capabilities. In other words, after performing the 400 meter walk, participants are asked to rate their confidence in their ability to walk, "…5 laps."

It is also important that participants evaluate their capabilities in the future, one week from now. In essence, participants are being asked to predict their confidence in what their capabilities would be one week in the future. Participants will most likely be quite fatigued from performing the 400 meter walk. It is important that they understand that they should evaluate their capabilities to walk the specific distances one week from now, not right now (post-400 meter walk).

Most participants will not be familiar with "laps" as a unit of measure. The administrator should expect participants to have some difficulty creating an accurate "perception" of the distance to be rated in each item. Administrators should make every effort to relate the item to the 400 meter walk (e.g., "…half the number of laps you just walked.

Responses are rated on a scale from 0 (no confidence) to 10 (complete confidence). Administrators mark the box that corresponds to participants' responses. Mark only 1 box per item.

Instructions

"You have just completed a walk that was [X]* laps. Please answer the following questions that concern your confidence (or certainty) in being able to walk at a similar pace for different distances *one week from now*." ***(Show response card PRMS#1).*** Please respond with a number between 0 (no confidence) and 10 (complete confidence)

Items:

1. How much confidence do you have in your ability to walk 5 laps, at the same pace, one week from now?
2. How much confidence do you have in your ability to walk the 10 laps (the same distance that you did today), at the same pace, one week from now?
3. How much confidence do you have in your ability to walk 15 laps, at the same pace, one week from now?
4. How much confidence do you have in your ability to walk 20 laps (about ½ mile), at the same pace, one week from now?
5. How much confidence do you have in your ability to walk 25 laps, at the same pace, one week from now?

Self-efficacy for Barriers to Active Living

The purpose of this scale is to assess participants' confidence in their capability to maintain their physical activity program when faced with a number of barriers or challenges. Each item represents a different barrier and the responses range from 0 (no confidence) to 10 (complete confidence). Administrators should read the instructions exactly as they appear and place a check in the box that corresponds with the participant's response. Check only one box per item.

Instructions

As noted above, this particular interview may possess high potential for unmasking. Thus, administers should read the below script prior to the instructions for the measure.

"Some of the questions I am going to ask may sound strange, but I would like to remind you again, that for scientific reasons, please don't tell me to which of the two LIFE groups you were assigned."

"If you decided to be physically active on a regular basis, how confident are you that you could maintain your physical activity under the following conditions?"

It should be noted that not all participants are involved in a formal or regular physical activity program. The scale should be completed AS IF THE PARTICIPANT DECIDED TO PARTICIPATE IN A REGULAR PHYSICAL ACTIVITY PROGRAM. Thus, the participant may have to imagine or pretend that they are involved in a program.

Not all items are relevant for all participants. For example, one barrier is "bad weather." A participant may complete all of his/her physical activity indoors and, thus, s/he may feel that weather may not be relevant. If the item is not relevant to the participant, the administrator should encourage the participant to answer as honestly and accurately as possible as it applies to him/her.

Body Satisfaction

The purpose of this scale is to assess participants' satisfaction with their physical functioning OVER THE LAST 4 WEEKS. Each item reflects a different aspect of physical functioning, such as "level of fitness" (item #1); "overall level of energy" (item #5). Responses can range from (very dissatisfied) to (very satisfied). Be sure to read the stem, "In the past 4 weeks, how satisfied have you been with…" before each item

Instructions

The following questionnaire asks you to rate how satisfied you are with different aspects of your physical function over the past 4 weeks. Please respond to each question by placing the appropriate number from the following rating scale in front of each item.

"In the past 4 weeks, how satisfied have you been with…"

Response scale:

- Very satisfied
- Somewhat satisfied
- A little satisfied
- Neither satisfied or dissatisfied
- A little dissatisfied
- Somewhat dissatisfied
- Very dissatisfied

It is important to note that this response scale is different than that used in the previous two scales; be sure to make this clear to the participant. It is also important to ensure that participants' evaluate their satisfaction OVER THE LAST 4 WEEKS. Thus, this scale aims to assess satisfaction with physical functioning for a relatively recent time frame. Be sure to read the stem, "In the past 4 weeks, how satisfied have you been with…" prior to each item. For example, "In the past 4 weeks, how satisfied have you been with you level of fitness?"

Desire for Physical Competence

The purpose of this scale is to assess an individual's incentive to be able to perform various physical tasks. Sample items include, "the ability to walk at a quick pace for a mile" (item #4), "the ability to do light work in the home or yard" (item #7).

Read the instructions carefully and exactly as written. As it states in the instructions, it is important to note that the scale is not concerned with "objective ability," or whether the participant is actually able to complete the tasks. Rather, the scale aims to assess the participant's level of desire to be able to do each task.

Responses for this scale can range from "no desire whatsoever" to "very strong desire". Place an X in the box that corresponds to the participant's response. Mark only one box per item.

Instructions

"Listed below are statements that describe different physical tasks. I will read each statement carefully and you tell me which response best describes your current desire to be able to perform each task. It is very important to remember that we are not interested in whether you can do the tasks or not; rather, we are interested in your level of desire to be able to do each task.

Response scale:

- No desire whatsoever
- Low desire
- Moderate desire
- Strong desire
- Very strong desire

Self-regulation

The purpose of this scale is to assess participants' traits or tendencies to regulate their own behavior. For example, "I work hard to achieve my goals" (item #2); "If I set goals, I keep close track of my progress" (item #5). Participants asked to rate the degree to which each statement applies to them. Read the instructions and the response scale carefully and place a check in the box that corresponds with participants' responses.

Please note: the participant may not agree or disagree with the statement. A response of "neutral" is allowed for this scale.

Instructions:

"I will read several statements about how people behave that may or may not apply you. Please tell me the degree to which you agree or disagree with each statement. You can completely disagree, completely agree, or decide somewhere between the two."

Response scale:

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly Agree

25.5.7. Mini-Mental State Examination (MMSE)

Description

- Brief, objective and quantitative measure that is used to assess cognitive functioning.
- Assesses orientation to time and place, recall ability, short-term memory, and arithmetic ability.

Materials Needed

- Test Administration Booklet
- Participant Booklet for response to questions 9 and 10
- Pencil
- Wrist watch
- Extra paper
- "Close your eyes" sign

Tips for Administering the MMSE

1. Orientation

Orientation to Time:

- Includes the first 5 questions under Orientation.
- Asks about year, season, today's date, day of the week and month.
- Score 1 point for each item answered correctly.
- If near the transition between 2 seasons, accept either season as correct (e.g. late August – accept summer of fall; early March – accept winter or spring).
- Some geographical regions have no clear seasonal changes. Accept common local references such as dry season, rainy season, planting season, etc.

Orientation to Place:

- Includes the last 5 questions under Orientation.
- Asks about state, county, city or town, building name or type, and floor of the building in which the examination is taking place.
- Alternative words that refer to place can be substituted as long as they are appropriate for the setting and are presented in order of increasing geographic precision:
    - State – province
    - County – borough, parish
    - City or town – part of the city or neighborhood
    - Floor of the building – room number or street address
- If done in an individual's home, then type of room could be substituted for floor of the building.
- Score 1 point for each item answered correctly

2. Registration

- Tests ability to learn and retain 3 unrelated words, alertness and attentiveness
- Wait one second between each of the 3 words when reading them

- Order of the answers does not matter
- If participant does not successfully repeat all 3 words on the first trial, repeat them again up to 5 trials.
- Score 1 point for each correct answer (for a maximum of 3 points), **but score is based on the first trial only.**

3. <u>Attention and Calculation (Serial 7's)</u>

- Assesses attention and mental calculation abilities.
- After the participant gives an answer, say "Keep going" until he or she gives a total of five answers. **<u>No other type of prompting is allowed.</u>**
- An answer is considered correct if it is exactly 7 less than the previous answer, regardless of whether that previous answer was correct.
- Score 1 point for each correct answer.
- Maximum score of 5 for this section.

4. <u>Recall</u>

- Assesses ability to recall the three words previously learned.
- Do not repeat the three words -- no prompts, cues or hints.
- Order of the answers does not matter.
- Score 1 point for each correct answer.
- Maximum score of 3 for this section.

5. <u>Naming</u>

- Assesses participant's ability to recognize and name 2 common objects.
- If pen, pencil, watch are not available, other common objects can be substituted (e.g., eyeglasses, chair, keys).
- Answer is correct whether participant identifies the whole object or only a part of the object.
- Score 1 point for each object correctly identified.

- Maximum score of 2 for this section.

6. <u>Repetition</u>

- Assesses ability to precisely repeat a series of unrelated words that are not frequently said together.
- Articulate clearly so all the plural "s" endings are audible.
- The phrase may be repeated if the participant has difficulty hearing or understanding the interviewer. Repeat up to 5 times if needed.
- If the participant repeats the entire phrase correctly, score 1 point for this section. If the phrase is not repeated exactly, the score should be zero.
- Score should be based on the participant's **first** attempt to repeat the phrase.

7. <u>Comprehension – (3 stage command)</u>

- Assesses ability to attend to, comprehend and carry out a complex 3-stage command.
- If physical limitations prevent the participant from either using his or her right hand, it is acceptable for the individual to use his or her left hand.
- If physical limitations prevent the participant from placing the paper on the floor, it is acceptable to instruct them to place the paper on a table or other accessible surface.
- Paper needs to be given to the participant with no preference to right or left hand.
- Each part of the 3-stage command gets 1 point if it is completed correctly.
- The paper does not need to be folded perfectly in half to be considered correct.
- Maximum score of 3 points for this section.
- If participant doesn't take the paper at all, score 0 points for this section.

- If physical limitation prevents participant from doing one or more of the required actions, score 0 points and note the reason why he or she did not perform the task.

8. <u>Reading</u>

- Assesses ability to read and understand a simple sentence.
- Use the provided laminated card.
- It is acceptable for participant to read aloud, but credit is given only if the eyes are closed without prompting.
- Score 1 point if the participant closes his or her eyes.
- If vision or illiteracy problem prevents participant from reading, score 0 points and note the specific reason.
- Maximum score of 1 point for this section.

9. <u>Writing</u>

- Tests ability to write a coherent sentence.
- If participant doesn't respond to the command to write a sentence, say "Write about the weather."
- Maximum score of 1 for this section.
- Sentence is correct if the sentence contains a subject and verb and is comprehensible.
- Ignore errors in grammar or spelling.

10. <u>Copying</u>

- Assesses visuospatial ability.
- Maximum score of 1 for this section.
- Size of the drawing does not matter.
- Drawing must have two 5-sided figures that intersect to form a 4-sided figure to get credit.
- Lines do not have to be perfectly straight.
- Participants with physical limitations should be given 0 points but the specific reason should be noted on the form.

Maximum score of 1 for this section.

25.5.8. Medication Inventory

The Medication Inventory should be completed during the first pre-randomization screening visit.

Many older adults use both prescription and non-prescription pharmaceutical products. The use of these products is of interest for several reasons. Their use is an important indicator of overall health, and the nature of the drugs taken is a strong indicator of clinically manifest disease. The response to the interventions may be enhanced or diminished by some drugs. Finally, individuals who use nutritional supplements, herbs or other complementary products may have stronger sense of health self-efficacy, and thus the use of these products could be related to study adherence.

All participants are asked to bring all prescription and non-prescription medications taken in the past two weeks to their first pre-randomization screening visit in their original containers with medication label. Medications include: pills, tablets, drops, salves, injections, creams/ointments, inhalers, suppositories and dermal patches. Non-prescription medications include: vitamins, aspirin, laxatives, dietary supplements, and herbal preparations.

Ask whether the participant has taken any prescription or non-prescription medications in the past 2 weeks. If not, check NO and move on to the next assessment form.
Otherwise, transcribe the complete name, strength and units, of each product, exactly as it appears on the medication label, to the Medication Inventory. Transcribe the name, strength and units, and code the formulation from what is written on the medication label. For tablets and capsules, which are the most common formulations, units are usually provided in mg (milligrams).

Write the name of each medication on a separate line. Do not record medications that have not been taken during the past two weeks. Record the names of all medications
After the prescription medications have been transcribed, continue to the non-prescription (i.e. over-the-counter) medications and supplements. Record the manufacturer's name of all vitamins and herbal preparations. The strength of herbal preparations and multi-vitamins should coded as Permanently Missing (PM)

If the participant did not bring in their medications, ask to see their medication list. If a list is not available, ask the participant to recall all the prescription and nonprescription medications that they have taken during the past two weeks.

25.5.9. Medical and Hospital Admission History

Medical and hospital admission history should be obtained during the first pre-randomization screening visit. This information will allow us to accurately describe the health history of our study population and to determine whether persons with specific health problems or conditions are more or less likely to benefit from the study interventions.

Overnight hospitalizations include acute care admissions for medical, surgical or psychiatric problems and/or procedures. Staying in an emergency room overnight is not considered a hospital admission. An admission to a rehabilitation facility is not considered a hospital admission.

For the chronic conditions, a Yes or No response is preferable. The Suspect or Possible response category should be used only if the doctor had told the participant that he/she might have the condition. If the participant is unsure, Don't Know should be marked.

Q14 under Chronic Conditions refers to non-hip fractures.

Q21 under Chronic Conditions includes amputation of a leg above or below the knee, but does not include amputation of toes or foot.

Responses that should trigger physician review are indicated with asterisks.

25.5.10. Quality of Well-Being Scale – Self-Administered (QWB-SA)

Instructions for Reviewing the QWB-SA for completeness and accuracy. Patients will self-administer the questionnaire. To be completed at home before Screening Visit 2 (or ancillary studies) and before each subsequent follow-up assessment (6-, 12-months).

General Instructions

1. Make sure the participant ID label matches the ID assigned to the participant who completed the form.

2. Verify the "date completed" with the participant, and make sure it is a feasible date (in the previous 2 weeks). The participant should have received the form at either a screening visit or in the mail 2 weeks prior to their assessment visit.

3. For Part I, Sections A and B, review each page to make sure that a Yes or No box is clearly checked for each question. If neither of the boxes or both boxes are checked, please ask the participant to answer the question at that time. These are chronic symptoms and should not change since the "date completed".

4. For Part I, Section C, Part II and Part III, review each page to make sure that each question was answered with "No Days" or any combination of "Yesterday", "2 days ago", or "3 days ago". However, if "No Days" is checked, no other boxes should be checked for that individual question.

5. For Part IV and Part V, the same rules apply as above for the response choices "No Days", "Yesterday", "2 days ago", or "3 days ago". **However, Part IV, Question 9 should be blank, unless the participant reported that they spent all or most of the day in a wheelchair in the previous question (Part IV, #8). If #8 is "No Days" then #9 should be blank.**

6. For Part V, Question 3, make sure a description of the problem is provided if "Yesterday", "2 days ago", or "3 days ago" are endorsed.

7. Provide initials and date to show that form was reviewed.

25.5.11. Health Care Utilization Questionnaire

This questionnaire is self-administered by the participant and is completed at home before Screening Visit 2 (or ancillary studies) and before each subsequent follow-up assessments (6-, 12-months).

Instructions

1. The forms are printed in both English and Spanish versions. Use the appropriate form for the participant.

2. Place the participant ID label on the front page of the questionnaire.

3. **Note: Participants will complete the QWB-SA at the same time as the Health Care Utilization Questionnaire. Always send them out and collect them together.**

4. Give participants both questionnaires along with the cover letter at the end of Screening Visit 1. They will bring the forms back at Screening Visit 2 or at an ancillary study. ****Participants should avoid completing the questionnaires in the 2 or 3 days following an ancillary study.**

5. Two weeks prior to the 6- and 12- month follow-up assessments, **mail** both forms with a cover letter to each participant.

6. Leave the date blank. This is completed when participant brings form to their next visit.
7. Research staff should be assigned to collect and briefly review the forms at the beginning of Screening Visit 2 or ancillary studies and the 6- and 12-month follow-up assessments. Review the forms for completeness. Clarify all missing and unclear responses. Forward the form to Data Entry.

8. Data Entry: Key-enter the form.

File the form in the participant's file.

25.5.12. Community Healthy Activities Model Program for Seniors

Volume of moderate physical activity will be measured as kcals/week and assessed using the Community Healthy Activities Model Program for Seniors (CHAMPS) physical activity questionnaire (PAQ). The reference for this instrument is:

Stewart et. al. "CHAMPS Physical Activity Questionnaire for Older Adults: outcomes for interventions." *Med. Sci. Sports Exerc.*, Vol. 33, Nol. 7, 2001, pp. 1126-1141.

This document describes the operational protocol for administering the CHAMPS PAQ in The LIFE Study. The rationale underlying a formalized protocol for administering the CHAMPS PAQ is based on the fact that, in the present study, the CHAMPS is administered by interview rather than being self-report. This protocol contains guidelines and specific instructions that are intended to reduce measurement variability due to the manner in which the instrument is administered.

Data Collection Intervals

The CHAMPS PAQ is administered during the 2nd clinic visit (SV2), 6-,, 12-, 18-month follow-up visit. All participants should complete the instrument during these time points.

Personnel responsible for administering the CHAMPS PAQ

The CHAMPS is used to measure volume of physical activity at baseline and follow-up. As such, the instrument may be administered only by research personnel who are blinded to the intervention assignment of study participants.

Moreover, the instrument may only be administered by research associates who have received training on this protocol, and are certified/approved to administer the instrument (see Chapter 24-Quality Control for certification requirements/form). Administration of the CHAMPS by personnel who are unmasked to a participant's intervention assignment or who have not received training on this administration protocol will invalidate the data collection and result in the data collected in such a manner as being coded as "Missing" in the study data base.

At the time of data collection, the research associate who administers the CHAMPS PAQ will

1. ***record his/her staff ID on the data collection form***
2. ***record any notes regarding problems with or questions about the administration of the instrument on the CHAMPS form.***

Administration site

The CHAMPS PAQ should be administered in an environment that is appropriate for conducting a confidential, person-to-person interview. Extraneous factors that could potentially influence a participant's reporting of physical activity should be minimized; these factors include disruptive noise, uncomfortable ambient environmental conditions, etc. It is recommended, although not required, that the CHAMPS PAQ be administered to all participants, at all data collection timepoints, in the same location to minimize any potential effect differences in the site of the interview might have on reported physical activity. If possible, the CHAMPS PAQ should be administered in a small, private room or office that is reserved exclusively, at the time of the interview, for administering the instrument.

The instrument may be administered via telephone or at a participant's residence if the participant is unwilling or unable to visit the study clinic for data collection. In these cases, the site of the data collection should be noted on the "Visit Disposition Form".

IV. Operational guidelines

Introduction

In administering the CHAMPS questionnaire, a major effort should be made by the person conducting the interview not to be judgmental of patients' responses. There is no right or wrong answers to any specific question being asked. It is important to set a positive, non-threatening tone and to put the participant at ease at the beginning of the interview. It is also important not to let the participant side track you. It may be difficult for some study participants to recall their activity over the past month. Some may not try very hard, and others get bogged down in details. You should strive to achieve a happy medium. You should control the pace of the interview; extraneous talk should be avoided. If participants are going into excessive detail, you should remind them that they need not account for every minute but that an average or estimate is expected. For example, you might ask, "How much time in general? or "about how long?"

It is important to realize that most of the participants you see will spend a vast majority of their waking hours in doing light activity. Many tiring and unpleasant household or occupational tasks do not have a very high energy cost. Also, for activities that are moderate or strenuous, it is very important to accurately determine the actual time spent doing the activity. For example, many older adults will go walking but stop to talk to a neighbor or to let their dog check out some nearby post! People play golf for 5 hours may be walking as little as 1 hour! Thus, when patients say that they do an activity on average 2.5 hours a week, it is very important to probe and to be certain that then are active for the entire time.

Overview of the Interview

1. The CHAMPS PAQ should be administered at the beginning of the data collection visit, to minimize the effect that mental or physical fatigue, time urgency, etc. might have on a participant's responses.
2. The interviewer should precede data collection with a brief explanation of the instrument and its rationale.

   For follow-up visits only, assessors should inform participants that it is important to report all physical activity when responding to CHAMP questions; that is, activity performed in conjunction with the LIFE Study or any activity that they may be doing on their own, independent of the LIFE Study. Assessors should indicate to participants that the amount of physical activity they may be doing will not unblind them as long as they do not tell them where the activity is being performed:

   I will ask you about various activities that you may have done in the past four weeks; for those activities that you have done, I will also ask you how many times you have done the activity and how many total hours you spent doing the activity. I also may ask you some questions about the activities you report doing to get a better understanding of those activities and to make sure we gather the most accurate information. There are no "right" or "wrong" responses, so please answer each questions as honestly and accurately as you can. (For follow-up visits only.) <u>Although for scientific reasons, I ask that you not tell me to which of the two LIFE groups you were assigned, when responding to questions in this interview, please report all of your activity, whether the activity is or is not part of the LIFE intervention. As long as you do not tell me what group you are in, this information will not un-blind me.</u> Do you have any questions?"

   If the participant cannot respond or understand the questions, go to Q44.

3. Not all items on the CHAMPS PAQ are included in the scoring algorithms for the instrument; participant responses to the items not included (items 1-6, 8, 11-13, 17-18) should be recorded on the interview form but do not require clarification or verification as the other items might. Items that ARE included in the instrument scoring algorithms, and which require clarification or verification on "Yes" responses, are ***bolded,*** on the data collection form.
4. For each item on the questionnaire, the interviewer will ask:
   "In a typical or "normal" week during the past four weeks, did you [INSERT ACTIVITY]."
5. If a participant has responded YES to an activity, then special care should be taken to ensure that a participant's reported activity corresponds to the CHAMPS definition of the activity. For example, participants who report performing "Heavy gardening" should have done heavy manual gardening tasks such as spading or raking. Using a tractor to till a small garden plot or spot-weeding a flower bed would not be interpreted as a "heavy gardening" task. Essential to this determination is an interpretation of the participant's activity intensity level; participants who report activities requiring MET levels $\geq$ 3 METS (items 7, 9, 14-16, 19, 21, 23-26, 29-33, 36-38, 40) should be asked to clarify the intensity level at which they perform the activity to determine if the activity conforms with the CHAMPS definition. The reason for this step is that positive responses to these questions have a substantial impact on the magnitude of a participant's final score.
6. It is extremely important not to count activities twice. One particular item that creates problems is item 25. Participants will give an estimate of how much time then walk up hills and then count this time again when asked how much time they spent in brisk walking. This item is meant to capture the activity of participants who hike uphill or walk up hills for extended periods of time. In general, this is a rare activity for most older adults.
7. If a participant's reported activity is not consistent with the CHAMPS definition for the activity, the interviewer will mark the appropriate

response box on the interview form and move to the next item. If a participant's reported activity does conform with the CHAMPS definition for the activity, the interviewer will mark the appropriate response box on the interview form and ask:

"How many times a week?"

8. For any activity that a participant responds "3", or more, times a week, the interviewer will follow-up with probes or clarifying questions to verify the accuracy of the reported frequency. Special care should be taken to ensure that a participant does not report intermittent bouts of activity occurring during an "activity session" as several discrete activities. For example, if a participant walks his/her dog every week for twenty minutes, but stops to talk with neighbors every five minutes, the participant should report a frequency of "1" rather than "3" or "4". Note that the interview needs to be able to discriminate between continuous versus multiple bouts of activity. **An activity is only counted as a discrete bout if it is performed ≥ 1 hour following a previous bout of activity.**
9. The interviewer will then ask:

   "How many total hours a week did you usually do "it" [or "this activity"]?

   It is very important to follow-up with probes or clarifying questions to verify the accuracy of the time spent in different activities. For example:

   Question 7: When people dance they often take breaks. Of the total time that you reported, how much of the time were you actually active?

   Question 9: Although people play golf for 5 hours, roughly half of the time is spent on the greens, some time is spent waiting for others to hit, and then there is time on the tee box. With this in mind, how much time would you estimate that you actually were walking between tees of from tee to green?

Question 19: When doing heavy work, it is common to stop and rest. If you think about the time that you have given me, what amount of it was actually spent digging or …?

Question 25: This question is reserved for people who consistently walk or hike up hills. If you walk up and down small rolling hills as part of your walking time, this will be counted later in the interview under walking (items 26-28).

10. At the conclusion of the interview, the interviewer shall review the data collection form for completeness and accuracy. Any notes regarding problems with or questions about, the administration of the instrument should be recorded on the "CHAMPS PAQ Administration" check sheet. In addition, the interviewer, before leaving the clinic for the day, should identify to the Project Manager and Principal Investigator any issues that may require review and/or adjudication. This notification should be made via email.

Scoring the CHAMPS PAQ

The scoring algorithms for the CHAMPS PAQ are detailed in the attached document, "***CHAMPS* Physical Activity Questionnaire (paq) Scoring Algorithms".**

Adjudication of Issues or Problems With CHAMPS PAQ Administration

When issues or problems with the CHAMPS administration are identified by an interviewer, the Principal Investigator will confer with co-investigators (principally the behavioral scientist on the study). Problem resolution, including date of resolution and any required protocol modifications, will be noted on the "CHAMPS PAQ Administration" check sheet and a list of adjudicated issues will be maintained by the Project Manager.

25.5.13. Late-Life Disability Instrument (LL-DI):

The Late-Life Disability Instrument (LL-DI) is an evaluative outcome instrument for community-dwelling older adults. The lack of sensitivity of existing outcome measures to detect important changes is a major limitation found in existing disability instruments that limits the thorough evaluation of interventions directed toward minimizing physical disability. Application of many current measures, not designed for evaluative purposes, often results in ceiling or floor effects. These effects occur if content in an instrument lacks sufficient breadth or if increments of item ratings are too global. The LL-DI is designed to overcome these limitations by using an item pool designed to include a comprehensive set of items that would be able to evaluate change.

What the LL-DI Measures:

Many physical functioning measures are organized along the singular construct of activities of daily living. Other physical measures are comprised of combinations of activity, endurance, and daily tasks that have no apparent structure or underlying framework. The result is conceptual confusion in the literature. These problems seriously limit the interpretation of results from studies evaluating the effects of physical interventions and research aimed at understanding the progression of late-life disablement. The LL-DI uses Nagi's disablement framework as the conceptual scheme to define item content. This self-report instrument is designed to assess and be responsive to meaningful change in disability. Disability refers to a person's performance of socially defined life tasks expected of an individual within a typical sociocultural and physical environment. A separate instrument (the LL-Function Instrument) measures functional limitations, defined as limitations in a person's ability to do discrete actions or activities.

The LL-DI items were written to encompass a wide variety of life tasks including: personal maintenance; mobility and travel; exchange of information; social, community, and civic activities; home life; paid or volunteer work; and involvement in economic activities. Item modification was based on a review of

existing disability instruments, a content examination by six experts in gerontology and rehabilitation, and suggestions by several focus groups of community-dwelling older adults. Following two field tests and subsequent analyses of the questionnaire, we retained sixteen of the original twenty-three items. In contrast to many disability instruments, we chose to write items without attribution to specific health concerns. Instead, we framed the disability questions in a more general fashion because we were interested in understanding factors other than (but including) health conditions (e.g. social and physical environment) that might influence disability outcomes.

Instructions

The LL-DI was designed for an interview setting, where an interviewer administers the questionnaire to the participant and gives the participant visual aids (large print outs of the response options) to guide in selecting the appropriate response. Self-administration of the instrument is also possible but may be problematical for those who have poor vision or writing difficulties. Disability refers to a person's performance of socially defined life tasks expected of an individual within a typical sociocultural and physical environment. The disability component of the LL-DI evaluates self-reported *frequency* of performing life tasks and *limitation* in capability of performing life tasks.

Frequency

Frequency describes the individual's regularity of participating in life tasks. Frequency questions are phrased, "How often do you *do a particular task*?" with response options of "very often," "often," "once in a while," "almost never," and "never."

Limitation

Limitation describes capability of performing life tasks. In order to address all factors that may influence limitation, the LL-DI defines limitation to include both personal factors (health, physical or mental energy) and environmental factors

(transportation, accessibility or socio-economic conditions). Limitation questions ask "To what extent do you feel limited in *doing a particular task*?" with response options of "not at all," "a little," "somewhat," "a lot," and "completely."

Directions for Administering the LL-DI Questions:

The interview should begin with the following script:

"In this set of questions, I will ask you about everyday things you do at this time in your life." There are two parts to each question. (Participants should report on their current functioning as best as they can characterize it.)

First, I will ask you *How often* you do a certain activity.

Next, I will ask you *To what extent do you feel limited* in doing this activity.

Explain each question and subsequent answer options:

For the first question (*How often do you do the activity?*), please choose from these answers:

Very often

Often

Once in a while

Almost never

Never

[Show visual aid to interviewee]

For the second question (*To what extent do you feel limited in doing the activity?*), please choose from these answers:

Not at all

A little

Somewhat

A lot

Completely

[Show the visual aid to interviewee]

For example, you might feel limited because of your health, or because it takes a lot of

mental and physical energy. Please keep in mind that you can also feel limited by factors outside of yourself. Your environment could restrict you from doing the things; for instance, transportation issues, accessibility, and social or economic circumstances could limit you from doing things you would like to do. Think of all these factors when you answer this section.

For each question, please select the one answer that comes closest to the way you have been feeling.

Let's begin."

25.5.14 400 M Walk Proxy Questionnaire

This instrument is to be used to assess the ability of a designated proxy (Spouse, significant other etc…) to evaluate the present walking ability of the participant and has been previously validated against directly determined 400 M walk performance

Please note: It is important that this instrument be completed as soon after the participant's visit or scheduled visit date (if they do not come in for the visit) as

possible. In case of a spouse, significant other, or friend attending the visit with the participant, the instrument can be administered at that point. **The participant should not be present when the interview is conducted on the proxy.** Be sure to read each item slowly, carefully, and **exactly as written**. Be sure to enunciate your words carefully and have patience with the proxy. This instrument can be completed in person or over the telephone.

Instructions

The interviewer should read the following script inserting the participant's first name into the [the participant] lines of the questions. "Now I am going to ask you a series of 9 questions about the current walking habits and abilities of [the participant]. Do you have any questions? Okay, let's begin."

Question 1: Be sure to indicate if the interview was conducted in person **(box a)** or over the telephone **(box b)**

Question 2: "In the past two weeks, has [the participant] done any walking outside the home? This would include walking in his/her neighborhood or in other parts of the city, walking in the mall or at the gym?"

Allow the proxy enough time to answer **Yes** or **No**. Only use the **D/K** response if they respond that they do not know. Indicate **REFUSED** if they refuse to answer the question.

Question 3: "When [the participant] walked in the past two weeks, what is the longest amount of time that he/she walked without sitting down to rest?"

Read the following test responses clearly to the proxy:

Less than 10 minutes

10 to 15 minutes

More than 15 to 30 minutes

More than 30 minutes

Only use the **D/K** response if they respond that they do not know. Indicate **REFUSED** if they refuse to answer the question.
If done over the phone, read each of the response categories; otherwise show response card DQ1.

Question 4: "When [the participant] walked in the past two weeks, what is the farthest distance he/she walked at one time without sitting down to rest?"

Read the following test responses clearly to the proxy:

Less than ¼ mile
(about 2-3 blocks)

¼ to ½ mile
(about 3-6 blocks)

More than ½ to 1 mile
(about 7-12 blocks)

More than 1 mile
(over 12 blocks)

Only use the **D/K** response if they respond that they do not know. Indicate **REFUSED** if they refuse to answer the question.

If done over the phone, read each of the response categories; otherwise show response card DQ2.

Question 5: "Because of a health or physical problem, does [the participant] have any difficulty walking a distance of one mile, which is about 8 to 12 blocks?"

Allow the proxy enough time to answer **Yes** or **No**. Only use the **D/K** response if they respond that they do not know. Indicate **REFUSED** if they refuse to answer the question.

Question 6: "Could [the participant] walk up and down every aisle in a grocery store without sitting down to rest or leaning on a cart?"

Allow the participant enough time to answer **Yes** or **No**. Only use the **D/K** response if they respond that they do not know. Indicate **REFUSED** if they refuse to answer the question.

Question 7: "Could [the participant] walk the entire length of an indoor shopping mall without sitting down to rest?"

Allow the proxy enough time to answer **Yes** or **No**. Only use the **D/K** response if they respond that they do not know. Indicate **REFUSED** if they refuse to answer the question.

Question 8: "Could [the participant] walk ¼ mile, that is about 3-4 blocks without sitting down to rest?"

Allow the proxy enough time to answer **Yes** or **No**. Only use the **D/K** response if they respond that they do not know. Indicate **REFUSED** if they refuse to answer the question.

Question 9: "Think about the past month. How much difficulty did [the participant] have walking for a quarter of a mile, which is about 2 or 3 blocks because of his/her health?"
Read the following test responses clearly to the proxy:

Usually did with no difficulty

Usually did with a little difficulty

Usually did with some difficulty

Usually did with a lot of difficulty

Unable to do

Usually did not do for other reasons

Only use the **Don't Know** response if they respond that they do not know. Indicate **REFUSED** if they refuse to answer the question.

After completing the interview, the interviewer should check the data collection form to make sure that all questions have a response.

25.5.15 Assistive Device Questionnaire

The Assistive Device Questionnaire asks whether the participant usually requires a cane or walker when walking inside and outside the home, respectively. Responses to these questions may ultimately be used in the adjudication process for the major mobility disability outcome, when data on the 400 m walk are not available. If the participant is not available, the questionnaire should be administered to the proxy informant.

25.5.16. Health Related Quality of Life (HRQL)

The below key components of health related quality of life are assessed at baseline and after 6 months and one year of follow-up. The stem questions for each section are to be repeated periodically as needed.

1. Depressive symptomatology is assessed with the Center for Epidemiologic Studies. Depression Scale (CES-D) a 20-item scale with four answer categories, queries about depressive symptoms experienced in the previous

week. Sixteen of the questions ask about the occurrence of symptoms and feelings associated with depression. For the questions asking about depressive symptoms, participants get 0 points if they rarely experience the symptom, up to 3 points if they experience the symptoms almost all of the time. Four questions are as about the frequency of positive feelings (questions 4,8,12 & 16). For these questions participants get 3 points if they rarely or never experience the symptom and 0 points if the experience the feeling most or all of the time. The maximum score on the scale is 60. Scores of 21 and higher are used as a clinical alert.

2. Sleep quality is assessed by means of the Pittsburgh Sleep Quality Index plus a question related to napping.

3. Energy and fatigue level is assessed by the 6 fatigue and energy items from the Modified Exercise-induced Feeling Inventory. Each item is rated on a 6-point, which focuses on the amount of time that individuals experienced fatigue or energy related feelings during the past week.

4. Pain is assessed using the 12-item pain scale as used in the FAST and ADAPT trials. The first six questions ask about the occurrence of pain the past week during a number of common physical activities. There are five response categories (always, almost always, sometimes, almost never, and never). These are followed by 6 questions regarding the intensity of pain during the same activities. There are six response categories (no pain, mild pain, discomforting pain, distressing pain, horrible pain, excruciating pain).

25.5.17. Cognitive Tests

A. Instructions

In LIFE Cognition, memory testing is conducted and scored by a LIFE Cognition certified interviewer. It is important that interviewers follow a standardized

procedure to ensure the data obtained from all field sites are reliable and valid. The way in which the testing is administered to a study participant can affect the validity of the responses to items. Therefore, it is important that the technician adhere strictly to the written guidelines in the test booklet and the following general tips for test administration.

B. Certification

1. Interviewer Information

To ensure standardization and validity of the administration of the LIFE Cognition neuropsychological test battery, the LIFE Cognition Coordinating Center (CC) requires each interviewer to become "certified". To become certified interviewers will need to:

- Audiotape an actual administration of the test battery on an age-appropriate person.
- Ensure that the administration booklet is completely filled out/scored.
- Mail original copies of the booklets and tape to the LIFE Cognition CC.

Quality Assurance staff at the Administrative Coordinating Center reviews the tapes and provides written feedback on the test administration. Written review indicates which tests that may need to be resubmitted for certification purposes. Sometimes, interviewers are certified on their first submission, however, if not, please do not get discouraged. The Administrative Coordinating Center is available to assist throughout this process.

Once certified, interviewers can begin administering the Cognitive Tests to participants.

2. Re-certification

Re-certification is a method of ensuring that the standards for certification and administration of the test battery are maintained throughout the study. Interviewers are reassessed at 6 and 12 months. The recertification process is the same as for initial certification, though data from an actual participant may be submitted.

3. Quality Assurance

As a part of ongoing quality assessment, tapes are randomly monitored. The Administrative Coordinating Center will maintain quality assurance (QA) by listening to 10% of all tapes submitted by interviewers on actual participants. A written review is provided on regarding the administration along with suggestions to enhance testing abilities.

C. LIFE Cognition Test Administration

1. Materials Needed for Testing

- □ LIFE Cognition Test Administration Booklet
- □ Cassette tape recorder
- □ Cassette tape and spare
- □ Batteries for cassette recorder and stop watch
- □ Sharpened pencils
- □ Pens
- □ Clip Board
- □ Stopwatch
- □ Wrist watch
- □ Laminated Testing Sheets
- □ "Close Your Eyes" (3MSE)
- □ Pentagon drawing (3MSE)
- □ Stroop Subtest 1
- □ Stroop Subtest 2
- □ Stroop Subtest 3
- □ Digit Symbol Substitution Test and Scoring Template
- □ Extra Paper

2. Prior to Starting Actual Testing:

- Assemble testing materials and equipment. Check equipment (tape recorder and stopwatch) to make sure the batteries are good. Keep extra batteries and tapes in the testing area.
- Label the audiotape with the participant ID number, acrostic, and date of testing.
- Explain that audio taping the session benefits the participant and the LIFE Cognition study. The purpose of the audiotape is to ensure that test administration and scoring are done correctly and consistently across sites. The audiotapes are erased once the data has been verified and entered in the computer database.
- If the participant refuses taping, make a note in the booklet and continue with the test administration.

To enhance standardization:

- Read all directions to the participant verbatim, both sample and actual test directions.
- Administer all tests in the order in which they are presented in the test booklet. The ***sequence of the tests is important*.**
- Record the participant's responses on the instrument *as* they are given.
- Audiotape each test administration. Interviewers should never depend on their memories to mark the participant's choices.
- Keep explanations to a minimum. Avoid interpreting or paraphrasing instructions or interview questions. It is easy to alter the meaning in this way.

3. Administration Instructions

- Make sure all writing in the test administration booklet is legible.
- Make sure participant information is completed at the top of each page of the test administration.

4. LIFE Cognition Visit

- Visit code should be entered in the space provided.

5. Test Administration Booklet

Booklet Key

- Each test contains instructions on Administration and Scoring.
- Each test contains a section where the interviewer should note if the test was administered
- or not and if no, the reason(s) it was not administered.

Trial complete? Y____ N____

If "no," give reason:

____Physical

___Vision

___Hearing

___Not cooperative/refused

___Other (specify)_____

Figures like this contain things the interviewer should say.

D. LIFE Cognition Test Battery
Rey Auditory Verbal Learning Test

Description

- Measures immediate memory span, provides a learning curve, reveals learning strategies or their absence, short-term and longer-term retention.
- Consists of five presentations with recall of a 15-word list, one presentation of a second 15-word list (Interference List B) with recall and a sixth recall trial of the first list. Long-term retention is then examined after a ten minute delay.
    - **Rey Order**
      Trial 1 – Immediate Recall, List A

Trial 2 – Immediate Recall, List A
Trial 3 – Immediate Recall, List A
Trial 4 – Immediate Recall, List A
Trial 5 – Immediate Recall, List A
Interference – Immediate Recall, List B
Trial 6 – Short Delay Free Recall, List A
Mark time – begins 10 minute interval (3MSE, Digit Symbol, Stroop done during this 10 minute interval)
After the 10 minute delay….
Long Delay Free Recall – List A

Materials Needed

- Test Administration Booklet
- Stopwatch
- Pen/pencil
- Watch or clock to note the time

Tips for Administration

- Read instructions verbatim. If the participant does not understand, instructions may be repeated..
- Pace is important. Read the words at an even pace, 1 second per word.
  - HINT ON TIMING: Tapping the foot along with saying the word will help keep an even, 1 second/word pace.
- After reading the list, wait at least 5 seconds for a response before offering encouragement.
- Do not provide information such as how many words are on the list or if certain words were recalled or repeated.
- Participant recall time for each trial is 1 minute (60 seconds).
- Check off words as remembered. The participant may repeat words more quickly than they can be checked off. When finished with the entire test battery, listen to the audiotape if unsure of a word.
- If the participant is silent for 10-15 seconds, ask “anything else?” or, if the participant indicates that he/she is finished, ask “anything else?”
- If the participant is frustrated, reassure them. “Remember, these tasks are meant to be challenging” or “Just do your best.”
- At the end of Trial 6 and at the beginning of the Long-Delay Free Recall, note the time. There must be at least a **ten minute delay** before the Long-Delay Free Recall.

Scoring

- The score for each trial is the number of words correctly recalled.
- Singular/plural variations are considered correct. Other variations of the word are not correct.

H. Modified Mini-Mental Status Exam (3MSE)

Description

- Expanded version of the original Folstein MMSE designed to increase the standardization, sensitivity, and specificity of the test as a screen for dementia.
- Assesses a broader variety of cognitive functions, covers a wider range of difficulty levels, and enhanced the reliability and validity of the scores.

Materials Needed

- Test Administration Booklet
- Pencil with eraser
- Stop watch
- Extra paper
- "Close your eyes" card
- Pentagon card

Tips for Administering the 3MSE

- Technicians should be thoroughly familiar with the testing procedures and scoring.
- Give at least 2 seconds for a response, but do not converse or offer extra help.
- If the participant says, "I don't know" or is unable to give an answer, prompt once with a statement such as "Please try," or "Give it a try."

- When the participant gives an incorrect answer, the technician should score accordingly and proceed to the next item.

Date and Place of Birth: Question 1

- Measures long term memory.
- Fill in the month, day, and year reported by the participant; convert the month into numerical format.
- If the participant gives a partial answer regarding place of birth, ask for the missing information.
- If an unrelated answer is given (e.g., hospital name) clarify the question by telling the participant that you are looking for the city/town and state or country in which he/she was born.
- If the participant gives a response, record the city/town and state/country and check "response given."
- SCORING NOTE: This question is repeated at the end of the test to verify the participant's response since the technician will have no source for determining the accuracy of the response. If the participant's response is the same for both questions, the answer is considered correct.

Registration: Question 2

- Say the three words distinctly at the rate of 1-2 seconds per word.

- If the participant repeats after each word is read by the technician, at the end of the presentation of all three words say, “Tell me the three words again” and mark the score according to the responses to this request.
- The exact form of the word must be repeated. Do not accept “shoe” for “shoes” or “modest” for “modesty.”
- Only score the first trial. However, record the number of presentations necessary for the participant to repeat the words (up to six – for a total of seven presentations).

Mental Reversal: Questions 3 & 4

- This question has two parts: counting backward from 5 to 1 and spelling WORLD backwards.
- For each part, ask the participant to do the forward version first; coach once when needed.
- Only one attempt per question is allowed.
- If the participant cannot spell “world” forward, prompt with “It is spelled W O R L D” at the rate of 1.5 seconds per letter.
- If the participant cannot count forward to 5, prompt with “Say 1, 2, 3, 4, 5” at the rate of 1.5 seconds per letter.

First Recall of Three Words: Question 5

- The words may be repeated in any order.
- For each word not readily repeated, provide the category followed by multiple choices when necessary. Do not wait more than 3 seconds for spontaneous recall and do not wait more than 2 seconds after given the category before providing the next level of help.
- If the participant gives an incorrect answer in the correct category (e.g., “socks” or “coat” instead of “shoes”), provide the three alternatives for them to choose from and score 1 when the choice is correct.
- If the participant repeats an incorrect form of the correct word, (e.g., “shoe” for “shoes”) score as correct word/incorrect form. In these cases it is very important to repeat the word with the correct ending back to the participant for the subsequent recall.

Temporal Orientation: Question 6

- Ask for the date. Fill in the month, day, and year reported by the participant. Convert the month into numerical form.
- Ask the day of the week. Write the response only if it is incorrect.
- Ask the season of the year. Write the response only if it is incorrect.
- Since distinctions between seasons can be difficult during certain months, the following table has been created. For months with two seasons listed, either answer is correct. Write the response only if it is incorrect.

Month	Correct Response
January	Winter

February	Winter
March	Winter or Spring
April	Spring
May	Spring
June	Spring or Summer
July	Summer
August	Summer
September	Summer or Fall (Autumn)
October	Fall (Autumn)
November	Fall (Autumn)
December	Fall (Autumn) or Winter

Spatial Orientation: Question 7

Write the response only if it is incorrect.

Question 7d assumes that the test is being administered in a clinic setting. When the correct answer is not among the three alternatives, substitute the correct response for the middle alternative (store).

If the participant responds that neither "clinic", "store" nor "home" is the correct answer, ask them to make the best choice out of the three options.

Naming: Question 8

- This set of questions tests whether or not the participant can promptly name the two objects and the five body parts.
- Correct responses for 8b: watch, wrist watch, or timepiece
- Correct responses for each body part are:
    - Forehead or brow
    - Chin
    - Shoulder or shoulders
    - Elbow or elbows
    - Knuckle or Knuckles
- If the participant cannot name the item within 2 seconds or gives an incorrect answer, do not help or question again.
- If the participant gives a scientific or medical version of the name for any of the body parts, ask him/her to provide the common name.

Four Legged Animals: Question 9

- Record each animal named in the spaces provided.
- Discontinue after 30 seconds. Record the total number of correct responses.
- If the participant gives no response in 10 seconds and there are still at least 10 seconds remaining, gently remind them (only once): "What (other) animals have four legs?"
- The first time an incorrect answer is provided, say "I want four-legged animals." Do not correct for subsequent answers.
- Accept marginal cases such as:

    - Monkey
    - Chimp
    - Baboon
    - Kangaroo
- Different names for the same animal of different age or sex count as one animal:
    - Kitten/cat
    - Puppy/dog
    - Deer/doe
- Other oddities:
    - A sea lion does not have four legs
    - A seal does not have four legs
    - A platypus is acceptable
- A set of abbreviations may be helpful for writing the animal names quickly.

Similarities: Question 10

- Question is designed to measure abstract or conceptual thinking. In general, 2 points are given for conceptual similarities, which are primarily pertinent for both members of the pair.
- Always accept the first answer given.
- If two concepts are given simultaneously (i.e., within the first statement provided back by the participant), score the higher value of the two concepts.
- If the initial response is scored "lesser correct answer" or "error/refused" coach the participant by saying "An arm and a leg are both limbs or extremities" to reinforce the correct answer.
- **Coach only for Question 10a.** No other prompting or coaching is allowed.

Repetition: Questions 11 & 12

- Pronounce the individual words distinctly but with normal tempo of a spoken sentence.
- No credit is given if the participant misses the "s".

Read and Obey: Question 13

- Hold up the card and say "Please do this."
- It is acceptable for the participant to read the sentence aloud. The participant is only scored on whether he/she closes his/her eyes.
- As soon as the participant closes his/her eyes say, "Open."

Writing: Question 14

- Allow a maximum of 1 minute after the first reading of the sentence for scoring the task.
- If the participant is still working at the end of 1 minute, allow them to complete the task for the sake of maintaining rapport and morale. Mark

the 1 minute point on the product and do not credit for parts finished after 1 minute.
- Observe which had the participant uses to write and record on the form. This will be used in Question 16. If this question is not performed, ask the participant if he/she is right or left handed.

Copying Two Pentagons: Question 15

- Allow a maximum of 1 minute for the drawing.
- If the participant is still working at the end of 1 minute, allow them to complete the task for the sake of maintaining rapport and morale. Mark the 1 minute point on the product and do not credit for parts finished after 1 minute.
- Do not penalize for self-corrected errors, tremors, minor gaps, or overshoots.
- When gaps are found in the drawing, they are permissible if the shape of the pentagon can be perceived.

Three Stage Command: Question 16

- Refer back to Question 14 to determine whether the participant is right or left handed.
- Do not repeat any part of the command. If the participant requests a portion of the command be repeated, and it is felt appropriate to oblige for the sake of maintaining rapport, score according to the response(s) executed prior to repeating the command.
- If the participant reaches for the paper right after hearing the first portion of the command, the technician should move the paper away from the participant so it is out of reach and continue to state the next two parts of the command without interruption.
- The participant may hand back the paper with either hand.
- The participant may use both hands to fold the paper.

Second Recall of Three Words: Question 17

- Administer this question even if the participant scored “0” in Question 5.
- Words may be repeated in any order.
- Provide categories as needed, as in Question 5.

Validation of Birthplace: Question 18

- Ask this question only when a response was given in Question 1d and 1e.
- Score the response by checking against the response in Question 1d and 1e.

Special Problems: Question 19

If any physical/functional disabilities or other problems exist which cause the participant difficulty in completing any of the tasks, mark the box coded “yes” and record the nature of the problem.
If no special problems were noted, check “no.”

I. Digit Symbol Substitution Test

Description

- Assesses sustained attention, concentration, visuomotor coordination and motor persistence.
- Part of the Wechsler Adult Intelligence Scale-Third Edition (WAIS-III).
- Consists of 7 rows containing a total of 140 small blank squares, each of which contains a randomly assigned number from one to nine. Above these rows is a printed key that pairs each number with a different symbol. The participant is asked to fill in the blank spaces with the symbol that is paired to the number as quickly as possible for 120 seconds (2 minutes).

Materials Needed

- LIFE Cognition Test Administration
- Digit Symbol participant worksheet
- Stopwatch
- Pencils
- Scoring Template

Tips for Administration

- Read instructions verbatim.
- Do not proceed with the test until the participant understands and correctly completes the seven sample items. Instructions can be repeated up to 2 times.
- Begin timing once the sample and instructions are completed.
- Testing time = 120 seconds (2 minutes).
- Boxes must be done in sequence (left to right). It is important that the interviewer sit beside the participant in order to observe him/her closely. Do not sit on the participant's dominant side; if they are right handed, sit on their left.
- Out of sequence means clustering, grouping, or skipping around. For example, doing all of the 1's.
- If the participant begins omitting items, redirect him/her **only on the first omitted item**. Give no further assistance except (if necessary) to remind the participant to continue until instructed to stop.

Scoring

- Technicians should be seated so they can observe the participant closely. If the participant begins to work out of sequence FOR THE SECOND TIME (after being redirected the first time), place an "X" in the box after the last correctly completed symbol. **SCORING STOPS AT THIS SECOND "X"**.
- Do not give credit for items that are drawn incorrectly or completed out of sequence (in a clustering or grouping fashion).

- Use the Digit Symbol Scoring Template to check the participant's responses.
- Record 1 point for each correctly drawn symbol completed within the 120-second time limit.
- Responses to the seven sample items are not included in the score.
- A response is scored as correct if it is clearly identifiable as the keyed symbol, even if it is drawn imperfectly or if it is a spontaneous correction of an incorrect symbol.
- Maximum score = 133 points

J. Stroop Test

Description

- Assesses concentration and attention.
- Requires adaptive behavior as the participant must selectively process one visual feature while continuously blocking out the processing of others (e.g. required to say the color of the ink in which a word is printed instead of reading the printed word).
- Visual competence and literacy are important for this test.
- Contains three subtests:
    - Subtest 1 the participant reads the names of colors.
    - Subtest 2 the participant names the colors of colored rectangles.
    - Subtest 3 the participant names the color of the ink in which the words are printed.

Materials

- LIFE Cognition Test Administration Booklet
- Set of 3 Laminated Stroop Subtest cards
- Stopwatch
- Pen/pencil

Tips for Administration

- Read instructions verbatim**.** If the participant does not understand the directions, they may be repeated up to two times. If the participant still doesn't understand at this point, move on to the next subtest.
- Attempt all three subtests with every participant.
- Participant should be instructed to hold the subtest by the edges. Pointing with the finger is not allowed. The participant is also not allowed to use "aids" such as squinting in order to make the words blurry (Subtest 3).
- Before telling the participant to "Go ahead" make sure the Testing Administration Booklet is opened to the score sheet. This is important as the participant may begin naming words/colors quickly.
- As the participant responds, follow along in the Testing Administration Booklet. If the participant makes an error, circle the "E".

- If the participant makes an error and self-corrects, continue with test and **do not** count the self-correction as an error. If an "E" (error) is marked and the participant self-corrects, this is corrected by marking through the "E", writing the date and initials by the interviewer.
- After each subtest begins, if the participant starts over or stops suddenly, do not stop timing. Just say, "Please continue."
- For each subtest, the first three items (from left to right) are used as a sample and to determine if the participant understands the directions.
- Timing
    - Subtests 1 and 2 = 120 seconds (2 minutes)
    - Subtest 3 = 180 seconds (3 minutes)

Rules for Discontinuation

- Attempt all three subtests with every participant.
- If the participant appears to understand the directions and attempts the test, score as usual.
- Subtest 1 - If the participant cannot read the practice items as requested, skip to Stroop Subtest 2. Indicate the reason the subtest wasn't given by placing a check beside the appropriate reason.

Scoring

- Record the number of errors in each subtest (circle the E for error below the color). NOTE: The participant is allowed to spontaneously self-correct and self-corrections are not counted as errors.
- Record the number of correct responses in each subtest.
- Record the time (in seconds) it takes to go through each subtest.
- If the participant exceeds the time limit for a subtest, place an "X" in the box after the last correct response given on the score sheet.
- If the participant does not complete the subtests in the allotted time, put **DC** (Discontinued) on the line beside "Time to complete test".

K. Questions

If there are any questions have questions regarding LIFE Cognition administration or certification, or the technician needs to speak with someone from the Administrative Coordinating Center, please contact …

25.5.18. Health Event Interview

Preparation

Before administering the interview, the staff member should determine the last time the Health Event interview was administered. Typically, this will be 3 months earlier, but it may not be if a previous visit had been missed. This date is important because it provides a time reference for all the questions that are asked. For the 3 month interview, the date of the first screening visit should be used. Interviewers should not use phrases like, “Since the last time we talked, “because this may confuse participants who do not distinguish between assessment and intervention staff.

Have a stack of **Event Tracking** forms available when administering this interview. For a number of the questions, additional information may be needed to help in the requesting of medical records. These additional questions are on the Event Tracking form. The Event Tracking form should be completed as soon as it becomes clear from the Health Event form that one is needed.

Proxy Respondents

In some cases the participant may not be available for a given interview. In these situations attempt to administer the interview to the proxy identified by the participant. After contacting the proxy, explain who you are and why you are calling, and proceed to administer questions 1-16. Question 17 has to do with symptoms experienced by the participant and could not be reliably answered by a proxy. In some cases, information may be volunteered by contacts other than the named proxy. In these cases mark “Other” as the source of information on the form.

Maintain the Masking

It is important that the person doing the interview be masked from the intervention status. The first part of the script states**,** “Now I would like to ask about important health events you may have had since [the last visit date]. You

may have already told other LIFE staff about some of the events, but I would like to hear about them again. Also, for scientific reasons, please don't tell me to which of the two LIFE groups you were assigned." It is very important that the participant be deflected should he or she start to tell you about the group they might be in. Interrupt the participant and say remind them that for scientific reasons you are not allowed to know what group they're in.

Completing the Questionnaire

Questions 1 & 2 refer the mode of administration and whether the respondent or proxy is the source of information. If participants have died between visits, still try to complete questions 1-16 of the interview with the proxy. These events are still important to capture and will contribute to the comparison between the two groups.

Questions 3-10 elicit information on discrete health events that are also study outcomes: (fracture, heart problems, stroke, congestive heart failure, aortic aneurysm, peripheral artery disease, revascularization procedures and injurious falls). These events will only be classified as study outcomes after objective medical evidence substantiating their occurrence is found in medical records.

For each question ask whether the participant had an occurrence of the event since the last time the interview was administered. If they answer yes, complete the sub-questions requesting additional information. In each case, the form instructs the interviewer when to complete an Event Tracking form.

Question 11 asks about same day surgery other than outpatient coronary revascularization. This is not a tracked outcome of the study, but may be an adverse event.

Question 12 asks about falls and whether any of these were injurious. Any falls mentioned here would include any fall leading to fracture reported in Question 3c.

Question 13 asks about nursing home or stays in long-term or extended care facilities. This would include stays in rehabilitation units after discharge from an acute care hospital.

The occurrence of hypertension is also a tracked study outcome.
Question 14 asks about new diagnoses of hypertension over the reporting period.

Q15 asks about new diagnoses of cancer. While this is not a tracked study outcome it may be an adverse event. Cancer may have already been reported as a hospitalization on Questions 9. Record it here as well.

Q16 and Q17 ask about signs and symptoms related to expected adverse events that may occur during the study. Q16 specifically relates to problems so severe that a physician or other medical professional was consulted. Q17 asks about symptoms that may occur but not necessarily of a severity that it led to care-seeking behavior. When interviewing proxies it is not necessary to ask question 17 since a proxy is unlikely to be able to answer these questions reliably.

Completed forms should be data entered within one day of the interview and the Events Tracking forms should be forwarded to the medical records requester.

Event Tracking Forms

An event tracking form should be filled out whenever a masked staff member receives information indicating that a participant has died or experienced any of the outcomes tracked by the LIFE Study (hospitalization, fracture, or outpatient cardiovascular revascularization), either as part of the Health Events Interview or by other means (such as a proxy calling the clinic, or the ascertainment of death during a scheduling attempt).

More than one Event Tracking form may be required during a given interview. For example, if a participant reported going to the ER because of a fall and at t a later time reported being hospitalized overnight for congestive heart failure, two tracking forms should be filled out (one for each episode). However, if one event happens during the diagnosis and treatment of another event, only one event form needs to be completed For example, if during a hospitalization for a heart attack a participant falls and breaks a bone. Both diagnoses are part of one 'illness episode' and would be described in the single medical record. If a participant was admitted to one acute care hospital, and directly transferred to another acute care hospital, only one Event Tracking form should be completed. Use the dates of the first hospitalization in the boxes, but write the information of the second hospitalization in the margin. If a subject visits and ER (not admitted) and is transferred/admitted to another hospital, complete one Event Tracking form because this is one illness episode. Enter the admission information for the overnight hospitalization with a notation about the ER visit.

Completing the Event Tracking Form

The Event Tracking form should not be completed for stays in rehab facilities, skilled nursing facilities, nursing homes, extended care facilities, or psychiatric hospitals. Only treatment in acute care facilities should be documented. All deaths should be documented regardless of location.

Question 1 asks for the participant's name.

Question 2 asks how the event was reported. For example, if the event was ascertained on during the Health Events interview, check the first box (a). If the event came to be noticed by another avenue (review of obituary pages, for example) box e. should be checked. In this case the source of information should be indicated.

Question 3 asks for the type of event. The sections of the form to be filled out depend upon the kind of event. The sections are: overnight hospitalizations for reasons other than fracture, fracture, outpatient coronary revascularizations, and death. There are additional questions for the respondent on this form, so it should be available while either interviewing the participant or the proxy.

There should only be one form filled out for each illness episode. However, it may occur that there are multiple outcomes that occur during the course of one hospitalization. In this case the event should be tracked according to the reason for hospitalization but the fact that other events have occurred should be noted on the face of the Event Tracking form.

The more information that is collected on this form the easier it will be to obtain the relevant medical records. Thus, participants should be encouraged to provide as many relevant details of the hospitalization as possible. Staff should do their best to obtain accurate dates of treatment by asking subjects to find billing or other documentation with definitive dates and names of facilities.

Section I asks about overnight hospitalizations. Section II asks about fractures other than those requiring overnight hospitalization. The outcomes process requires radiographic evidence to substantiate the occurrence of a fracture. Therefore, it is important to document whether x-rays were obtained in a doctor's office, clinic or emergency room. Section III asks about outpatient coronary revascularizations. Revascularizations performed as part of a hospitalization are tracked in section I. Section IV asks about death, both in and out of hospital. If a death occurs during a hospitalization, document it in Section IV, not in Section I.

25.5.19. Cost-Effectiveness Analysis

In order to conduct the cost-effectiveness analysis the following steps are taken.

1. Quality of life assessment.
    a. QWB-SA scores are used at each follow-up.
    b. In the case of death, 0.0 is obtained as the QWB-SA score for each successive follow-up.
    c. Missing data is estimated using the last observation carried forward (LOCF) or the least squares estimation procedure.
    d. Quality adjusted life years are calculated by summing the difference between the QWB-SA scores for participation in the two arms of the study.
2. Cost: Administrative cost for the study is estimated using the method using the ACTIVE trial.
    a. Personal cost is estimated by multiplying the amount of time dedicated to the intervention activities by the prevailing hourly wage rate at the Wake Forest School of Medicine.
    b. Cost is estimated for program components including the computerized tracking system, peripheral materials, printing and postage, facilities costs, and health club membership.
    c. Direct cost to participants will include cost of athletic equipment, costs of treating injuries (based on prevailing charges from medical service at the Wake Forest School of Medicine) and other incidental costs.
    d. Time spent exercising is estimated from questionnaire information.
    e. Value of time spent in the program is calculated on the basis of the average wage of workers 20-64 years of age as reported by the Bureau of Labor Statistics. For participants older than 65 years of age, time spent exercising is valued on the basis of the average wage for workers 65 years or older according to the Bureau of Labor Statistics.
    f. Travel distances are estimated using software that calculates the distance traveled from the zip code of the patient's residence to the

facilities. Travel costs are estimated using the Federal Government's Reimbursement Rate per mile.

3. Health Care Utilization is estimated from the UCSD Health Care Utilization Questionnaire.
    a. The value of service is adjusted to 2004 dollars using the Medicare component of the consumer price index.
    b. Costs of medications are estimated on the basis of wholesale price in 2004 discounted by 15% (in order to adjust for typical retail acquisition costs). A dispensing fee of $2.50 is added for each 30-day period a medication is used.
    c. The costs of physician visits, ER visits, and hospital stays are valued at the prevailing charge rates for Wake Forest University.
4. Cost-Effectiveness Analysis
    a. The analysis we'll use an intention to treat principle.
    b. The average cost and the mean number of quality-adjusted life years gained and the associated 95% cost fund intervals are determined for each group.
    c. A ratio of cost/quality-adjusted life years is created.

(See Direct Cost Tracking Form in Appendix B.)

Appendix A

Dear LIFE Participant:

Thank you for participating in the LIFE research study. We sincerely appreciate your involvement in this important program.

In an effort to decrease the amount of time you need to spend at each assessment visit, we would like you to complete the 2 enclosed questionnaires prior to your next assessment visit. Please complete the questionnaires during the week prior to your next assessment visit and the forms are collected from you at that time.

Both questionnaires should take about 15 minutes or so but please take your time and do not hesitate to call us toll-free if you have questions. The toll-free phone number is _____. A questionnaire specialist can answer your questions between the hours of 10AM – 7PM Eastern Standard Time (7AM – 4PM Pacific). If no one is available at the time you call, please leave a message stating your name, phone number, and the best time to call you and your call will be returned within 1 business day or sooner if possible.

On both questionnaires there are general instructions but it is very important to read each question carefully since the pattern of questions may change suddenly. Some questions may seem to repeat previous material but each one is unique in some way and is necessary.

Some tips are as follows:

Quality of Well-Being Scale

1. Do not fill in any of the blank squares in the box at the top of the page that say “LIFE.”

2. Please complete all questions on this questionnaire in the same day.

Health Care Utilization Questionnaire

1. Do not fill in any of the blank squares in the box at the top of the page that says “LIFE.”

2. Please note that this asks only about the past **3 months**. Some visits are 6 months apart but we are only interested in health care you received in the 3 months prior to completing the form.

3. You don’t have to be 100% accurate so try to complete the questionnaire from memory. It is not necessary to review all of your medical receipts or records to answer these questions.

4. It is OK to have another person help you to complete the questionnaire if that works better for you.

Thanks again for your participation and we look forward to seeing you at your next visit.

Sincerely,

LIFE study staff

Appendix B

Cost-Effectiveness - Direct Cost Tracking Form

1. Personnel Cost - Please list all job titles, estimated hourly wage, and number of hours associated with the intervention. This includes office time for marketing the study, recruiting participants, encouraging attendance, arranging for facility access, obtaining equipment, etc.

a. Title _____Wage _____ Hours_____

b. Title _____Wage _____ Hours_____

c. Title _____Wage _____Hours_____

d. Title _____Wage _____ Hours_____

2. Facilities Cost - Please describe facilities used for any part of the intervention. Please include facility setting (indoor gym, outdoor pool), size of space, zip code of facility, total amount of time reserved or paid for, and estimated retail value in your area. Please include office space for administrative time related to conducting the intervention.

a._____

_____

_____

b._____

_____

_____

c._____

_____

_____

3. Equipment Cost - Please indicate the name, total number used or obtained, and estimated retail value of pieces of equipment related to the intervention.

a. Item _____Amount _____ Est. Value_____

b. Item _____Amount _____ Est. Value _____

c. Item _____Amount _____ Est. Value _____

d. Item _____Amount _____ Est. Value _____

4. Miscellaneous Materials - Please list all administrative materials (copying, pamphlets, phone charges) associated with the intervention.

a. Item _____Amount _____ Est. Value_____

b. Item _____Amount _____ Est. Value _____

c. Item _____Amount _____ Est. Value _____

d. Item _____Amount _____ Est. Value _____

5. Participant Costs not measured elsewhere - Please list any items paid for by the participants such as exercise clothes, bandaids, OTC meds, massage, chiropractic, health care utilization for injuries related to exercise (if not reported elsewhere).

a. Item _____Amount _____ Est. Value_____

b. Item _____Amount _____ Est. Value _____

c. Item _____Amount _____ Est. Value _____

d. Item _____Amount _____ Est. Value _____