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ACTIVE (Advanced Cognitive Training for Independent and Vital Elderly), 1999-2001 [United States]

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Form 700 AN1 Abbreviated Battery Questionnaire

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Question by Question Specifications Guide for Administration of the Abbreviated Testing Batteries for the 1st and 2nd Annual Post-Test Measurements

Forms 700 & 705 Level I

Form 710 Level II

I. Purpose

At the time of enrollment, ACTIVE study participants are 65 years of age or older, living in non-institutionalized settings but at risk of loss of functional independence. Because of the potential for a change in health status, functional status or residence, it is prudent to prepare for the possibility of follow-up testing with disabled/institutionalized participants or participants who relocate prior to completion of the study protocol.

In anticipation of these possibilities, ACTIVE Investigators have developed a two-tiered Abbreviated Testing Battery that can be used at the time of annual post-test visits.

II. Overview

When a participant cannot/will not agree to <u>full</u> participation at the time of an annual study assessment, the Field Site Staff must determine which measures, if any, can be completed.

A two tier abbreviated testing protocol has been designed. Measures included in **Level I** (the minimal data set) can be administered in approximately 75 minutes either in-person or as a telephone interview. Level I tests include the MDS-HC, Mobility Questionnaire (Mobility, Life Space, Falls), Driving Habits, Health Conditions, Health Services Utilization, SF-36, Medication Audit and the EPT.

The **Level II** battery includes all Level I measures <u>and</u> the AVLT Recall, Letter Series, AVLT Recognition, MMSE, Timed IADL and UFOV. It takes approximately 2 hours and forty-five minutes to complete all Level II measurements, i.e. 75 minutes for Part 1 plus 90 minutes for Part 2. At least two sessions are required, although several sessions may be necessary.

A few of the measures can be completed in a **Proxy Interview**. The following measurements may be completed with a proxy: MDS-HC, Mobility Questionnaire, Driving Habits, Health Conditions and Health Services Utilization and the Medication Audit. It takes approximately 40 minutes to complete the Proxy Interview.

III. Administration Protocol

The Abbreviated battery has been divided into two parts to meet both administrative and scientific objectives. All Level I measurements are included in the Part 1 battery. The measures included in Part 1 constitute the minimal data set and must be completed first, in their prescribed order, for

both Level I and Level II subjects. The Part 2 battery should always be completed <u>after Part 1</u> for Level II participants. A description of Parts 1 and 2 of the Abbreviated Battery appears below.

A. Part 1 of the Abbreviated Battery for both Level I and Level II participants (Form # 700 and Form # 705)

Note: Unique Part 1 instruments have been developed for use in 1st and 2nd Annual Post-Tests, Forms # 700 and # 705 respectively.

Part 1 of the Abbreviated Battery is considered the minimal data set. Measurements included in the Part 1 battery should be completed for both Level I <u>and</u> Level II subjects. Ideally, the Part 1 measurements will be conducted during an in-person session, although most can be conducted on the telephone if necessary. The only exception is the EPT, which must be completed as a self-administered measurement at the end of an in-person session or at home with mailed return. Inperson testing may be conducted at the established testing site, at the participant's home or at an alternate location. Testing sessions that occur at a health care institution (hospital, nursing home, etc.) may require special authorization from the institution, family member, an appointed guardian, or someone else.

1. Materials / Equipment Needed

The following items should be assembled in advance of the subject's appointment time.

- Abbreviated Battery, Part 1, **1**st Annual Post-Test, Form #**700** with ID label
- Abbreviated Battery, Part 1, **2nd** Annual post-Test, Form #**705** with ID label
- Medication Audit Form # 618;
- EPT Form #617 for in-person administration OR EPT Form #717 with a self addressed stamped envelope for take-home or mail-home administration
- Pencils for subject's use

4. Section by Section Review

Section A. Identifying Information for Part 1 of the Abbreviated Battery, Form # 700 and Form # 705

- **A1.** Study ID: Affix the subject's ID label in the space provided.
- **A2.** Visit #: Code this item prior to the start of measurements. The code for the 1st Annual Post-Test on Form # 700 is Visit # AB3, and the code for the 2nd Annual Post-Test on Form # 705 is Visit # AB4.
- **A2a.** Level: Code the correct Level of this assessment.
- **A3.** Form Version: Be sure the form version on the form matches the current approved version.

Sections Preceding Each Measure, Sections B, D, I, L, N, P

A standard set of questions has been added to the beginning of each of the measures in Part 1 of the Abbreviated Battery. A description of these questions follows here:

- Q1. Was the measurement completed at this follow-up? If the measurement was completed, code 'yes' and complete the rest of the questions in this section. If the measurement was not completed, code no and skip to the next measurement.
- **Q3.** Indicate the mode of the interview. Only modes allowed for the measure are included in the coding scheme for each respective measure. For example, it is not allowed to complete the EPT as a telephone interview so telephone interview does not appear as a category for this measure.
- **Q4.** Indicate with whom you completed the interview. Only allowable codes are listed for each respective measure. For example, it is not allowed to complete the SF-36 interview with a proxy so the proxy categories do not appear for this measure.
- **Q4a**. If a proxy is interviewed for any of the items in the measure, record a proxy code in this data field.

Section C: The MDS

No changes have been made to the procedures for administration of the MDS. Follow the procedures for administration of the MDS described elsewhere. This measure may be administered to a proxy.

Sections E, F, G and H: Life Space, Falls, and the Driving Questions

No changes have been made to the procedures for administration of these measures. Follow the procedures for administration of these measures described elsewhere. The Life Space and Falls questions may be administered to a proxy but the Driving Questions may <u>not</u> be asked of a proxy.

Sections J: Health Conditions Questions

No changes have been made to Section J. questions for Part 1 of 1st Annual Post-Test, Form # 700 and the procedures for administration of these measures. These measures may be administered by proxy.

New Section J. health conditions questions have been added for the 2nd Annual Post-Test and a unique Form # 705 has been developed for this purpose. These measures may be administered by proxy.

Form # 705, Section J. changes are as follows:

The purpose of questions **J1** (**a-p**) is to obtain a listing of chronic diseases diagnosed since the time of the participant's first telephone screener interview. Therefore, the time frame for these questions assumes an approximate **2-year** interval from the screener interview. The month and date of the **1**st **baseline contact** should be used to orient the participant to the time frame not the telephone screener date. Before the interview, be sure to determine the date you will use here.

Take the date from the upper right hand corner of the participant's VCS labeled, "1st Baseline Contact". Only the month and year of the 1st Baseline Contact should be used to orient the participant to the questions.

For example, if the participant responds 'yes' to a condition and the 1st Baseline Contact date is 06/12/1998, the Testers can <u>probe</u> "Is that since <u>June</u>, 1998?".

The stem question, "Since your first visit in _____ (MONTH/YEAR_OF 1st BASELINE CONTACT FROM THE VCS) has a doctor/nurse told you that you have...", is specifically worded so that the participant does not make up diagnoses. For example, the participant may have some difficulty seeing and think s/he has cataracts, but if s/he has not been told this by a doctor (nurse or Physician's Assistant), it should not be coded as 'Yes'.

J1q, J1r and J1s. If the participant answers YES to J1p, i.e. cancer(s) were diagnosed since the telephone screener interview, then these sub-questions should be asked. The three sub-questions are asked to obtain additional information regarding cancer types and treatments received. The questions allow recording information for up to three cancer types/organs, if <u>currently</u> receiving chemotherapy or radiation treatment and/or if chemotherapy or radiation treatment was received since the first interview ______ (MONTH/YEAR OF 1st BASELINE CONTACT). Recording sub-questions: For sub-questions J1q-s, enter in the first reported cancer type and then follow the arrows to the end of J1s. Do this for each cancer type listed.

Section K: Health Services Utilization Question

Follow the procedures for administration of these measures described elsewhere. These measures may be administered to a proxy.

Sections M: The SF-36 Questions

Administration of the SF-36 is different in the Abbreviated Battery. In this battery, it is administered as a tester-administered interview. Otherwise, no changes have been made to the questionnaire. It should not be administered to a proxy.

Section 0: The Medication Audit

No changes have been made to the procedures for administration of the Medication Audit. Follow the procedures described elsewhere. The Medication Audit may be administered to a proxy. As per protocol, Tester should use ACTIVE data form # 618 to complete this measure.

Section Q: The EPT

A few minor changes have been made to the EPT procedures. For the Abbreviated Battery, it may be taken home or mailed to the participant's home to be completed independently. Ideally, it will be completed during an in-person session. Testers should have the participant use form # 617 for in-person administration of the EPT. A new form, #717, has been developed for use when the EPT is sent home with the participant or mailed to the participant's home and completed independently. In addition, it is now permissible for the participant to receive physical assistance in recording responses to the questions in the EPT. Such assistance may be required for participants who otherwise may be unable to write their responses due to limited physical strength or stamina or limited motor control secondary to a paralysis or paresis.

The following changes have been made to the new EPT form # 717 for use in independent or athome administration.

- 1) Changes have been made to Section A to capture the ID/Initials of the person who distributes the form, the date of distribution and the date the form was returned.
- 2) A written introduction to Participants has been added and appears as page 2.
- 3) Participants are asked to record the date and time they start the test, items A8 & 9
- 4) Participants are asked to record the time they complete the test, item B30.
- 5) Participants are asked to record any break time, item B31.
- 6) Participants are asked to 'certify' that they completed the test on their own. Physical assistance in writing responses is allowed.
- 7) Finally, participants should be provided a self-addressed stamped envelope to return the EPT.

The following points should be included in a script or cover letter when distributing Form #717 to participants.

- 1) Thank the participant for agreeing to complete the EPT at home.
- 2) Provide the participant with a site contact name and phone number for use if s/he has questions.
- 3) Remind the participant that s/he should complete the EPT independently. Someone may provide physical assistance in writing responses if the participant is unable to write their own responses but no assistance is permitted for the actual content of the responses.
- 4) Provide the participant with a self-addressed stamped envelope and instruct them in how and when to return the completed EPT to the Study Center.
- 5) Set a date for the expected return of the EPT and continue to track all distributed tests until they are returned.

B. Abbreviated Battery Part 2, only used for Level II participants (Form # 710)

The measurements in Part 2 of the Abbreviated Battery <u>must</u> be conducted in-person. <u>None</u> may be completed with a proxy. Part 2 may be conducted at the field site's testing site, in the participant's home or an alternate location requested by the participant or determined by the study staff. Testing sessions that occur at a health care institution (hospital, nursing home, etc.) may require special authorization from the institution, family member, an appointed guardian, etc.

1. <u>Materials / Equipment Needed</u>

The following items should be assembled in advance of the subject's appointment time.

- Abbreviated Battery, Part 2 data form #710 with ID label attached
- AVLT Subject data forms packet #611a with ID label attached to all pages
- AVLT Post test coding form #611 with ID label attached
- Letter Series data form # 612 with ID label attached
- AVLT Recognition Form #613 with ID label attached
- The proper AVLT Audiotape

- MMSE supplies, i.e. wristwatch, 3 pieces of 8 ½ x 11 inch blank, white paper for completing directives, writing a sentence, and drawing shapes, 'Close Your Eyes' Show Card, pencil, and 'Intersecting Shapes' Show Card
- Useful Field of View supplies, i.e. computer, UFOV software
- Electronic timer
- Clock with digital display
- Ruler or 5 x 8 card for subject's use
- Sony Boom Box Model CFS-B15
- Pencils for subject's use

3. Order of Administration

The order of administration for the Part 2 testing session should be as follows:

- AVLT Recall (25 minutes)
- Letter Series (10 minutes)
- AVLT Recognition (5 minutes)
- MMSE (10 minutes)
- Timed IADL (17 minutes maximum)
- UFOV (20 minutes)

Part 2 must be completed <u>after</u> Part 1 measurements during an in-person session in one or more visits. If completed in one session, Part 2 should take approximately 90 minutes, not including a break. Although a break may be taken at the end of any test, testers should not split the session prior to the completion of the AVLT Recognition.

4. Section by Section Review

Section A. Identifying Information for Part 2 of the Abbreviated Battery, Form #710

- **A1.** Study ID: Affix the subject's ID label in the space provided.
- **A2.** Visit #: Code this item prior to the start of measurements. The code for the 1st Annual Post-Test is Visit # AB3; the code for the 2nd Annual Post-Test is Visit # AB4.
- **A3.** Form Version: Be sure the form version on the form matches the current approved version.

Sections Preceding the Measures, Sections B, F, H, J

A standard set of questions has been added to the beginning of each of the measures in Part 2 of the Abbreviated Battery. A description of these questions follows here:

Q1. Was the measurement completed at this follow-up? If the measurement was completed, code 'yes' and complete the rest of the questions in this section. If the measurement was not completed, code no and skip to the next measurement.

c. Section C: AVLT Recall

No changes have been made to the procedures for administration of the AVLT Recall measure. Follow the procedures for administration of the AVLT Recall documented in the 1st Annual Post-Test materials. This measure may <u>not</u> be administered to a proxy.

d. Section D: Letter Series

No changes have been made to the procedures for administration of the Letter Series measure. Follow the procedures documented elsewhere. This measure may not be administered to a proxy.

e. Section E: AVLT Recognition

No changes have been made to the procedures for administration of the AVLT Recognition. Follow the procedures documented in the 1st Annual Post-Test materials. This measure may <u>not</u> be administered to a proxy.

f. Section G: MMSE

Essentially no changes have been made to the procedures for administration of the MMSE. No eligibility scoring is required for the Abbreviated Battery. Follow the procedures documented in the QxQs for the Baseline Individual Assessment Part I Screening session. This measure may not be administered to a proxy.

g. Section I: Timed IADL

No changes have been made to the procedures for administration of the Timed IADL. Follow the procedures documented elsewhere. This measure may <u>not</u> be administered to a proxy.

h. Section K: UFOV

No changes have been made to the procedures for administration of the UFOV. Follow the procedures documented elsewhere. As always, if the participant has a physical limitation that makes it difficult for him/her to touch the screen, the participant may verbally respond and the Tester may touch the screen for him or her. This measure may not be administered to a proxy.

D. The Proxy Interview

Selected tests/interviews in the Abbreviated Battery may be completed with a proxy. Proxy interviews may be conducted on the telephone or in-person, either at the field site's testing site, at the participant's home, at the proxy's home, or an alternate location. All tests that may be completed with a proxy are included in Part 1 session. Unique Part1 instruments have been developed for proxy use in the 1st and 2nd Annual PT, Forms #700 and #705 respectively. Form #700 and #705 clearly indicates which measures may be completed with a proxy. The text of the sentences will need to be altered a bit to accommodate the proxy interview.

1. <u>Materials / Equipment Needed</u>

The following items should be assembled in advance of the proxy interview.

- Alternate Visit Form # 902 with ID labels attached
- Abbreviated Battery, Part 1, 1st Annual PT form #700 with ID label attached
- Abbreviated Battery, Part 1, 2nd Annual PT form #705 with ID label attached
- Medication Audit Form # 618

2. Order of Administration

The order of administration for the Proxy Interview should be as follows:

- MDS (15 minutes)
- Life Space/Falls (10 minutes)
- Health Conditions (5 minutes)
- Health Services Utilization (5 minutes)
- Medication Audit (10 minutes)

Ideally, a proxy interview will be completed in a single session.