Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE)

Cognitive Assessments Manual

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Interviewing Guidelines

1. INTRODUCTION

Participants will be administered a brief battery of neurocognitive tests in the baseline GRADE examination and again in Year 4 and Year 6. The first assessment will establish a baseline for cognitive functioning in GRADE participants, which with repeated cognitive measurements in the subsequent exams will provide the opportunity to identify risk factors associated with change in cognitive functioning over time.

These cognitive measures were chosen for their broad but efficient coverage of major cognitive domains. The measures of cognitive function administered in the GRADE baseline examination include the Spanish English Verbal Learning Test (SEVLT), the Word Fluency Test of the Multilingual Aphasia Examination (letter F for English speakers, P for Spanish speakers, and Animal Category), and the Digit Symbol Substitution Test of the Wechsler Adult Intelligence Scale-Revised (WAIS-R). These measures tap several cognitive domains: verbal learning and memory, word fluency, and psychomotor speed, respectively.

The following are general guidelines for interviewing, procedures for handling specific difficulties, and special considerations for conducting a cognitive assessment.

2. OVERVIEW OF PROCEDURES

The ultimate goal of the research interview is the standardized and reliable collection of data. The interviewer plays an important role in serving as the human conduit of information from participants to the database. The way the interviewer conducts the interviews both facilitates and standardizes the gathering of the data. The following are some of the important roles of the interviewer.

A trained examiner administers the cognitive function tests in a fixed order, one right after the other, in a quiet room. The tests are administered following the instructions printed on the Cognitive Assessment forms. Test results are tabulated by the interviewer after the participant has completed the tests and left the room.

The order of test administration is as follows: (1) Spanish English Verbal Learning Test, (2) Word Fluency Tests, and (3) Digit Symbol Substitution Test. Ideally, all the tests should be administered in the same session. In the contingency that the testing cannot be completed in a single session, the separate tests should be completed as close to each other as possible in time. If the battery of tests cannot be completed within a 6-month period of the study visit, whether in parts or all at once, the Neurocognitive assessment cannot be completed. In other words, for all the tests to be considered part of a single session, they must be completed within 6 months, the less interval the better.

The testing environment and examiner's behavior should be geared toward optimizing the participant's performance on each of the cognitive measures.

Prior to the visit and at the time of testing, please ask the participant if he/she uses reading glasses or wears a hearing aid. If so, these items should be worn during testing. Second, you need to assess GRADE Cognitive Manual Version 5/1/2021

whether hearing and vision are adequate or inadequate for optimal performance. These decisions are made from self-report by the participant AND also from observations made by the interviewer in the field.

To rate vision as adequate or inadequate, ask the participant if they wear glasses, and if so, if they have them. If they do not have them, ask if they need glasses for reading. If they need glasses and do not have them, but can clearly see and copy the symbols in the Digit Symbol, then vision is adequate. If they say they do not need glasses but cannot distinguish the symbols correctly, then mark vision as inadequate.

To rate hearing as adequate or inadequate, ask the participant if they wear a hearing aide. If not, ask if they have problems with their hearing. Their hearing is inadequate if you have to scream, or repeat questions, regardless of whether they have a hearing aide or not. Their hearing is adequate if they do not have a hearing problem both from self-report and observation during interview. The testing room must have a table with sufficient workspace and appropriate lighting for the participant to comfortably complete the Digit Symbol Substitution Test.

A good quality stopwatch is necessary to time components of the cognitive function exam. The stopwatch should be simple to use, easy to read, and preferably one that allows the examiner to begin and end timing silently (some stopwatches produce a sound upon starting and stopping).

Timing should always be as discrete as possible to avoid producing anxiety and affecting test results. Although time limits are set for some tests, the participant should not be told of any time limit on any measure, unless they ask.

<u>Please have this manual with you during every test administration</u>. *Always read scripts exactly as written*. The scripts found at the end of your manual may be used in place of the manual **only after** you have become familiar with all test procedures and administered the battery a few times. It is best to use this manual as you administer each test so that you are able to prompt appropriately as needed. Each participant should be allowed to attempt every task, unless it is determined that the participant cannot do the task due to an obvious physical impairment.

Participants are often curious as to how well they did. Although scoring does not take place during testing, the interviewer should provide general encouragement, and reassure each participant who asks that he/she did as well as others who have taken the tests. Do not indicate to the participant whether specific responses are correct or incorrect.

Most participants will feel challenged, however, some may feel insecure and others possibly hostile. It is important for the interviewer's attitude to be friendly, non-threatening, reassuring and supportive throughout the testing. Examiners should be sensitive to provide positive reinforcement (e.g., "you're doing fine") after each test if appropriate.

Complete the Participant Assessment Information Section, Part A, of the NEURO FORM Questionnaire before the cognitive assessment. Complete the Cognitive Assessments Summary Section, Part B, of the Cognitive form Questionnaire (NEURO FORM) after the participant has finished the cognitive tests and left the exam area.

Record a three-letter-initial identification code of the interviewer completing this form corresponding to the interviewers first, middle and last name. If an interviewer does not have a middle name, write in an "X". For example, John Smith's identification code would be "JXS".

Introduction to the Cognitive Assessment

Begin the introduction of the GRADE cognitive assessment with the following script,

English Script: "In the GRADE study, we will test your memory three times, during this visit and again in Year 4 and Year 6 of the study. This is a unique opportunity to see how diabetes treatment is linked to problems in memory and other mental abilities. In this part of the interview, I will give you a couple of short tasks that will require memory and concentration. We only ask you to do your best and put your best effort. Please know that no one gets all of them correct."

Spanish Script: " GRADE ha decidido hacerle una prueba de la memoria tres veces, ahora, y después durante el cuarto año y el sexto año de la investigación. Esta es una oportunidad única pare ver si el tratamiento de la diabetes afecta la memoria y otras habilidades. En la siguiente parte de la entrevista le voy a hacer algunas preguntas y le voy a dar un par de actividades cortas que requerirán de su memoria y concentración. Quiero que trate de poner su mayor esfuerzo en todas las pruebas. La mayoría de las personas que hacen estas pruebas no contestan todo correcto, nada mas trate lo mejor que pueda."

If a participant asks about the measures/tests or is concerned about their memory, say:

English Script: "The tests used to assess memory and cognition in GRADE are for research purposes only. They are not meant to be used for clinical diagnosis. In others words, this is not information that a doctor could use to treat you. However, if you are concerned about your memory or mental abilities in general, we will provide you with names and contact information of specialists that can make a clinical evaluation and address your concerns."

Spanish Script: "Las pruebas que usamos para medir la cognición y memoria en GRADE son solamente para propósitos de esta investigación. No están diseñados para hacer un diagnostico medico. En otras palabras, no provee información que un doctor podría usar para su tratamiento medico. Sin embargo, si usted esta preocupado por su memoria o habilidades cognitivas, podemos darle nombres e información de especialistas que pueden llevar a cabo una evaluación medica y atender a sus preocupaciones."

It is recommended that each GRADE site identify specialists in cognitive disorders in case a participant wants to have a clinical evaluation of cognition.

2.1 Spanish English Verbal Learning Test (Assessment A)

The Spanish English Verbal Learning Test (SEVLT) is a measure of new learning and verbal memory. The participant is asked to recall a list of 15 common words over three trials. For each trial, the participant is read the list and asked immediately afterwards to recall as many of the words as they can. Next, a new distracter word list is presented and the participant is asked to repeat each word. After the presentation of the distracter word list, the participant is asked to recall the first list again.

The first 15-item word list is presented in three learning trials.

English Script: "First, I am going to read a list of words to you. I want you to listen carefully and try to remember the words as I read them. When I stop, I would like you to recall as many of the words as you can. You will not be able to remember all of the words so just do the best you can. You do not have to recall the words in the same order that I read them. Are you ready?"

Spanish Script: "Primero, le voy a leer una lista de palabras. Quiero que escuche cuidadosamente y que trate de recordar las palabras a medida que las leo. Cuando me detenga, me gustaría que recordara tantas de las palabras como usted pueda. Tal vez, no podrá acordarse de todas las palabras, simplemente haga lo más que pueda. No tiene que recordar las palabras en el mismo orden que yo las leo. Listo (a)?"

Say each word distinctly at the rate of ~ 1.5 seconds per word.

If participant repeats the words after you, say "Just listen. Do not repeat after me."

Spanish Script: "No tiene que repetir las palabras, solo escuche."

Script: "Now tell me all of the words you can remember."

Spanish Script: "Ahora dígame todas las palabras que usted pueda recordar."

Immediately after these instructions, start the stopwatch. Timing should be discrete to avoid creating anxiety or a sense of time pressure.

To record the words recalled, write out the words as they are being recalled in the appropriate column for each trial including repetitions and intrusions (words that were not on the list). Words do not have to be recalled in the order in which they were read.

Recalled words are considered correct only when stated in the language in which the examiner provided the words. If the participant begins to produce the recalled word in another language say "**Please tell me the word in English.**"

Spanish Script: "Por favor dígame la palabra en español. "

Once the participant has produced as many words as he/she appears able to recall <u>or</u> after 15 seconds, with no response provide one prompt, "Anything else?", in Spanish "¿Alguna otra palabra?" for additional words before going on to Trial 2.

Do not allow more than 60 seconds for recall for any trial.

The word list is repeated for Trial 2.

Script: "I am going to read the same list of words to you again. I want you to try to remember as many of the words as you can, including those you have recalled before. When I stop I want you to recall as many of the words as you can remember."

Spanish script: "Voy a leer la lista de palabras otra vez. Escuche cuidadosamente y cuando yo termine dígame tantas de las palabras como usted pueda recordar."

Present the 15-item word list.

Script: "Now tell me all of the words you can remember."

Spanish Script: "Ahora dígame todas las palabras que usted pueda recordar."

Discretely start the stopwatch.

To record the words recalled, write out the words as they are being recalled in the appropriate column for each trial. Include repetitions and intrusions. (Words do not have to be recalled in the order in which they were read.)

Once the participant has produced as many words as he/she appears able to recall <u>or</u> after 15 seconds with no response, provide one prompt, "Anything else?", in Spanish "¿Alguna otra palabra?" for additional words before going on to Trial 3.

Do not allow more than 60 seconds for recall of Trial 2.

The word list is repeated for a final time in Trial 3.

Script: "I will read the same list again. Listen carefully and when I finish tell me as many of the words as you can remember."

Spanish script: "Voy a leer la misma lista de palabras una vez más. Escuche cuidadosamente y cuando yo termine dígame tantas palabras como usted pueda recordar."

Present the word list.

Script: "Now tell me all of the words you can remember."

Spanish Script: "Ahora dígame todas las palabras que usted pueda recordar."

Discretely start the stopwatch.

To record the words recalled, write out the words as they are being recalled in the appropriate column for each trial including repetitions and intrusions. Words do not have to be recalled in the order in which they were read.

Once the participant has produced as many words as he/she appears able to recall <u>or</u> after 15 seconds with no response, provide one prompt, "Anything else?", in Spanish "¿Alguna otra palabra?" for additional items before presenting the Distracter list.

Do not allow more than 60 seconds for recall of Trial 3.

Next, the new (Distracter) list of 15 words is presented.

Script: "I am going to read you a different list of words. This time, I want you to repeat each word out loud after I read it.

Spanish script: "Ahora, voy a leer una lista diferente de palabras. Esta vez, quiero que repita cada palabra en voz alta después de que yo la lea."

Present each word and pause for the participant to repeat it. If the participant does not repeat a word, prompt for the correct response. Do not correct any mispronunciations or errors during this trial, as the primary purpose of the words is to serve as a distraction, and participants will not be required to recall these new words at any point.

Following the presentation and repetition of the distracter items, immediately ask the participant to recall the 15 items from the first list presented.

Script: "Now, I want you to tell me as many of the words from the <u>first</u> list that I read to you as you can remember. That is the list that I read to you three times."

Spanish script: "Ahora, quiero que me diga todas las palabras de la <u>primera</u> lista que yo leí como usted pueda recordar, la lista que leí tres veces."

Discretely start the stopwatch.

Do not repeat the first list.

If the participant says that he/she cannot remember any of the words on a given trial, encourage him or her by saying, "Just give it a try" or "Take a moment to see if any of the words come to mind".

Spanish Script: *"Trate a ver si puede", "Tome un momento a ver si alguna de las palabras le vienen a la mente."*

To record the words recalled, write out the words as they are being recalled in the appropriate column for each trial including repetitions and intrusions. Words do not have to be recalled in the order in which they were read.

Once the participant has produced as many words as he/she can recall, provide one prompt for additional items, say "Anything else?". Spanish Script: "¿Alguna otra palabra?" Or "See if you can think of anymore". Spanish Script: "Trate a ver si puede pensar en otra mas." Do not allow more than 60 seconds for recall.

2.1.1. Spanish English Verbal Learning Test (Scoring and Discontinuation)

The number of correctly recalled words, repetitions and intrusions for each of the three learning trials (Trials 1-3,) and the delayed recall trial (Trial 4), is recorded on the Neurocognitive Summary Scoring Form (Section B of the NEURO FORM) by the examiner after the participant has left the exam area.

Types of responses

<u>Correct:</u> Recalled words are considered correct only when stated in the language in which the examiner provided the words.

<u>Repetition</u>: A repetition is scored each time any response (whether a target word or intrusion) is repeated in the same trial. If the participant appeared to be repeating responses as a way of self-cueing, do not score it as a repetition error.

<u>Intrusion</u>: A response is classified as an intrusion error when the word is not on the target list, that is the list of words presented over trials 1-3.

In the column "Resp Type" short for 'Response Type' record a "C" for correct words, record an "I" for an intrusion or record an "R" for a repetition next to each word recalled. An intrusion that is repeated is considered a repetition.

The following is an example of a set of responses after presentation of the word list, the response type, and how to record each response type.

Response Type	Record
Correct	С
Correct	С
Correct	С
Intrusion (a word not on the list)	I
Correct	С
Correct	С
Repetition (of a word <u>on</u> the list)	R
Repetition (of a word <u>not on</u> the list)	R
Intrusion (a word not on the list)	I
Correct	С
Repetition (of a word <u>on</u> the list)	R
Total Correct	6
Total Repetitions	3
Total Intrusions	2
	Correct Correct Intrusion (a word not on the list) Correct Correct Repetition (of a word <u>on</u> the list) Repetition (of a word <u>not on</u> the list) Intrusion (a word not on the list) Correct Repetition (of a word <u>on</u> the list) Correct Repetition (of a word <u>on</u> the list)

The SEVLT may be discontinued due to participant refusal or if the examiner determines that the participant is unable to perform the task due to a physical impairment such as hearing loss.

If discontinued, the reason is recorded in Section B, item 1a, of the Neurocognitive Scoring Summary Form (NEURO FORM).

2.2 Word Fluency Test (Assessment B)

The Word Fluency Test is a measure of verbal functioning. In this task, participants are asked to produce as many words as possible that begin with the letter F (letter P for Spanish speakers) within a time limit

of 60 seconds for each letter, avoiding names of persons or places, variations of the same word such as plurals or past tense, and repetitions.

Explain the task to the participant.

Script: "On this next task, I will say a letter. Then I want you to tell me as many different words as you can think of, as fast as you can, that begin with that letter. There are only two exceptions. First, you may not say names of people and names of places. So, if I were to say "T," you could say words like 'table,' 'take,' or 'turtle' but could not say words like 'Thomas,' or 'Texas'.

Spanish Script: "En la siguiente actividad, voy a decir una letra y quiero que me diga, lo mas rápido posible, todas las palabras en las que pueda pensar que comiencen con esa letra. Solamente hay dos excepciones. Primero, no diga nombres de personas ni nombres de lugares. Por ejemplo, si yo dijera la letra "T," usted puede decir palabras como 'tabla', 'tomar' o 'tortuga' pero no puede decir palabras como 'Tomás', o 'Tijuana'."

Pause.

Script: "The second exception is that you may not say the same word with a different ending. For example, if you said 'take,' then you could not say 'takes,' or 'taking.' It's really the same word with different endings.

Spanish script: "La segunda excepción es que no puede decir la misma palabra con diferente terminación. Por ejemplo, si usted dice 'tomar', entonces no puede decir 'tomaron' o 'toman' porque es la misma palabra con diferente terminaciones."

Pause.

Script: "Tell me as many words as you can that begin with the letter F. I will tell you when to stop. Go as quickly as you can. Ready, begin!"

Spanish script: "Dígame tantas palabras como pueda pensar que comiencen con la letra P. Yo le diré cuándo detenerse. Listo(a), empiece."

Discretely start the stopwatch when the participant provides the initial response and record the participant's responses verbatim.

If after approximately 5 seconds, the participant gives no words, then begin stopwatch and repeat the basic instructions, say,

"Remember please tell me as many words as you can that begin with the letter F."

Spanish Script: "Recuerde, dígame tantas palabras como pueda que comiencen con la letra P."

No extension on the time limit is made in the event that the instructions are repeated.

If at any time during the 60 seconds the participant cannot think of any more words, wait quietly for 10 seconds. After 10 seconds of silence prompt for more words, say:

"Can you think of any other words that that begin with the letter F?"

Spanish Script: "¿Puede pensar en otras palabras que comiencen con la letra P?"

Do not stop the test until the entire 60 seconds is over.

A participant may stop producing words because he/she feels he/she made an error (e.g., repeated a word or said a name of person or place). In this instance, prompt the participant to continue, saying: "that's okay; just go on". Spanish Script: "Esta bien, siga."

The examiner may clarify the instructions only when the participant has clearly misunderstood the instructions and is only providing inadmissible words such as only stating names of people or places.

If a participant provides an incorrect response, they may be re-instructed not to provide names of persons or places, variations (e.g., run, runs, running), or words starting with an incorrect letter. Each of these error types may be corrected (queried) only **once within** each 60 sec. trial. You can say,

Queries for errors

If they provide name of person or place: "Remember, no names of places (people)

Spanish Script: "Recuerde, no diga nombres de lugares (personas)."

If they provide variation of a word: "Remember, not the same word with a different ending." Spanish Script: "Recuerde, no use la misma palabra con diferente terminación."

If they provide a word starting with a different letter: **"Remember, tell me words that begin with the letter F."**

Spanish Script: "Recuerde, dígame palabras que comiencen con la letra P."

If the participant repeats a previous word, do not interrupt; simply circle the error.

The examiner should never interrupt the exam to correct repetition errors.

If the person provides two responses of a word that are homonyms (e.g., "for", "four"), these are treated as two correct responses only when provided consecutively. If these words are spaced out with at least one word in between, the second instance must be scored as a repetition unless the person spontaneously indicates that they are referring to a different word (e.g., "the other kind of for"). Do not query in these situations.

Query words that can be both proper names and regular nouns <u>at the end of the 60 sec. interval</u>. Some examples are "frank", "polo" and "ford". For example, if the participant says "frank", at the end of the 60 sec. interval you should ask: **"What did you mean when you said 'frank'? Spanish Script:** *Qué quiso decir cuando dijo__*?

While recording the words, if the examiner cannot keep up with the words produced and misses a word, but is certain that the participant produced an admissible word, place an "X" on the line to indicate the participant should receive credit for the word. If the examiner does not understand a word the participant said, wait until the end of the trial to query. You can say: "What did you mean when you said....", or "I did not quite understand the word..." or "Could you please confirm a word you said. It sounded to me like you said (insert word)"

Spanish Script: "¿Que quiso decir cuando dijo...?", "No entendí cuando dijo la palabra...", "Puede confirmar una palabra que usted dijo. Creo que escuche que dijo (insert word).."

After 60 seconds has passed, the examiner stops the test, provides encouragement, and introduces the next task, category fluency.

Category fluency is a measure of verbal fluency and semantic knowledge. It assesses ability to generate exemplars from a category provided by the examiner. Fluency in the animal category is assessed. Participants are allowed 60 seconds to generate names of animals.

Say to the participant,

"Now, I want to see how many different animals you can name. Any animals will do; they can be from the farm, the jungle, the ocean or house pets. They can begin with any letter. Go as quickly as you can. Ready, begin!"

Spanish script: "Ahora, quiero ver cuantos animales diferentes usted puede nombrar. Cualquier animal esta bien; puede ser de la finca, de la selva, del océano o animales domésticos. Los nombres pueden comenzar con cualquier letra. Vaya lo mas rápido posible. Empiece."

Discretely start the stopwatch when the participant provides the initial response and record the participant's responses verbatim.

If after approximately 5 seconds, the participant gives no response, then begin stopwatch and repeat the basic instructions, say, "**Remember, please tell me as many animals as you can. They can begin with any letter**".

Spanish Script: "Recuerde, dígame cuantos animales como usted pueda. Pueden comenzar con cualquier letra."

If at any time during the 60 seconds the participant cannot think of any more words, wait quietly for 10 seconds. After 10 seconds of silence prompt for more words, say: "Can you think of any other animals?"

Spanish Script: "¿Puede pensar en otros animales?"

If they provide a non-animal word, say "Remember, give me names of animals."

Spanish Script: "Recuerde, dígame nombres de animales."

After 60 seconds has passed, the examiner stops the test.

2.2.1 Word Fluency Test (Scoring and Discontinuation)

After the participant has left the room, the examiner must proof all the responses for admissibility. The examiner should finish writing out any words that were not completely written out during the exam. Clarify any words that may have been unclear during the time the test was given. If unable to spell the word, write it out phonetically. Check any ambiguous words in the dictionary or *dictionary.com* for example (only after the participant has left the room).

If the participant is **not literate** and reports that they are unable to do the test, it should be scored as impairment in the scoring sheet. However, do not assume that an individual with no or few years of formal education cannot do the task; in fact, people who cannot read or write can do well on this task.

Some participants who cannot read or write will refuse to attempt the test, but you will be unable to determine if they would be able to produce words if they were to attempt the task. In this case, it should be scored as "refused".

The total score for each trial is the number of correct words produced, and does not include repetitions, perseverations, or other incorrect responses (as defined below).

<u>Repetition</u>: A repetition is scored when a word is repeated within a 60-second trial (e.g., friend, fame, fantastic, *friend*).

<u>Perseveration</u>: A perseveration is scored when the participant provides a response that is incorrect, but that would have been acceptable for a previous trial (e.g., providing non-animal "F" words during "ANIMAL" fluency). Perseverations are scored for the 'F' fluency trial if the participant perseverates on the stimuli used (i.e. "T" words) in the example.

<u>Incorrect</u>: Responses that are incorrect include names of people or places and any other response that is incorrect and is not a repetition or perseveration. These are not scored in the summary form.

The next table below shows examples of responses for both Letter fluency and Animal category.

Set of responses for Letter Fluency		Set of responses for Animal Category	
Formula	correct	Cheetah	correct
Funny	correct	Lion	correct
Fantastic	correct	Mouse	correct
Fantastical	incorrect	Horse	correct
Fragment	correct	Funny	perseveration ('f" word)
Formula	repetition	Tiger	correct
Forever	correct	Tiger lily	incorrect
Phenomenal	incorrect (starts with "p")	Cheetah	repetition
Take	perseveration	Ferret	correct
Turtle	perseveration	Friend	perseveration ('f" word)
Fantastic	repetition	Rabbit	correct
Total correct	5	Total correct	7
Total Repetitio	ons 2	Total Repetitions	1
Total Persever	ations 2	Total Perseverations	2

Letter Fluency

Circle any inadmissible words, i.e., proper names of person or places, variations (e.g., change in suffix such as "ed"), incorrect words, perseverations and repetitions.

Record the number of correct words, repetitions and perseverations on the Neurocognitive Scoring Summary Form (Section B of the NEURO FORM).

Homophones (i.e., words that sound like they are spelled with F (P for Spanish) but actually begin with another letter) are incorrect. For example, phenomenal, physical or photosynthesis. Do not correct a participant if they make a phonemic error.

The instructions include a specific prohibition against giving different forms of the same words. In scoring this measure, it is useful to keep in mind the purpose of the test: It is to measure verbal fluency. Hence, if two words seem similar, but they are clearly separate words, give credit for both. If two words seem similar because they are a simple derivation of the word, or the same word with an added suffix (e.g., -s, -ed, -ing, -ly), the second word should be considered a repetition.

Slang terms are admissible if in general use.

In the case that the participant begins to give a numerical series (e.g., 51, 52, 53, 54...), only the first number is counted as correct. Numbers that are not a series (e.g., 4, 5, 40, 50) are counted as correct.

Foreign words (e.g., fauxpaus, passé, lasagna, pasta, Lebensraum) are correct if they can be considered part of the English lexicon, the criterion being their listing in a Standard English dictionary.

Words which are capitalized but are not specifically names of persons or places will be counted as correct: Fauve, Friday, French, February, etc.

Cases where the examiner is unclear about scoring should be referred to the Columbia University Cognitive Coordinating Center for clarification.

Category Fluency

Score as you would score Letter Fluency, including total correct, perseverations, and repetitions. **Specific responses for** *animals*:

<u>YES</u>	<u>NO</u>
Dinosaur	mythical or imaginary beasts
Fish	unicorn
Birds	Pegasus, etc.
Bestia* (Spanish)	Teddy bear
Insect	Man, women, child

* accept if referring to a mare, not if referring to a beast

- Listing species (e.g., poodle, cocker spaniel, Springer spaniel, Doberman) is acceptable. Another example is monkey, orangutan, baboon, etc.
- Listing a species general name and various types of a species are all acceptable. For example, fish, cod, trout, salmon, shrimp, etc. are all correct.
- If the participant gives the male and female of an animal, only count one. Examples are "chicken", "rooster" or "gallo", "gallina" in Spanish.

The Word Fluency Test may be discontinued due to participant refusal, task difficulty (i.e., meaning the participant never understood the instructions), or if the examiner determines that the participant is unable to perform the task due to a physical impairment such as hearing loss.

If discontinued, the reason is recorded in Section B, item 2.a. of the Neurocognitive Scoring Summary Form (NEURO FORM).

2.3 Digit Symbol Substitution Test (Part D)

The Digit Symbol Substitution Test (DSST) is a measure of psychomotor speed and sustained attention. In this task, the participant is asked to translate numbers (1-9) to symbols using a key provided at the top of the test form.

Present the instructions deliberately and at a slow pace.

Hand the participant a pencil without an eraser. Place the digit symbol form in front of the participant, point to the key above the test items and read the script.

Script: "This last task is the digit-symbol task. Look at these boxes. Notice that each box has a number in the upper part and a special mark in the lower part. Each number has its own mark."

Spanish script: "Esta última actividad es la actividad de dígitos-símbolos. Mire estas casillas. Note que cada casilla tiene un número en la parte de arriba y una marca especial en la parte de abajo. Cada número tiene su propia marca."

Point to 1 and its mark, then to 2 and its mark.

Script: "Now, look down here to where the boxes have numbers in the top part, but the squares at the bottom are empty."

Spanish script: "Ahora, mire aquí abajo adonde los cuadros tienen números en la parte de arriba, pero los cuadros de abajo están vacíos."

Point to the sample items.

Script: "I want you to put in each of the empty squares the mark that should go there, like this."

Spanish Script: "Quiero que coloque la marca que debe ir en cada uno de los cuadros vacíos, así."

Point to the first sample item, then to the mark below the 2 in the key.

Script: "Here is a 2; the 2 has this mark. So I put it in this square, like this."

Spanish Script: "Aquí hay un 2; el 2 tiene esta marca. Entonces, lo coloco en este cuadro vacío, así."

Write in the symbol in the first sample square. Then say:

Script: "Here is a 1; the 1 has this mark." Spanish Script: *"Aquí hay un 1; el 1 tiene esta marca."*

Point to the second sample item, then to the mark below the 1 in the key.

Script: "So I put it in this square." Spanish Script: *"Entonces, lo coloco en este cuadro."*

Write in the symbol in the second sample square. Then say:

Script: "This number is 3; the 3 has this mark." Spanish Script: *"Este número es el 3; el 3 tiene esta marca."*

Point to the third sample item, then to the mark below the 3 in the key.

Script: "So I put it in this square."

Spanish Script: "Entonces, lo coloco en este cuadro"

Write in the symbol in the third sample square.

After marking the first three samples items, say:

Script: "Now, you fill in the squares up to this heavy line."

Spanish Script: "Ahora llene usted los cuadros hasta que llegue a esta línea gruesa."

If the participant makes an error on a sample item or skips a box, correct the error immediately and review the use of the key. Continue to help (if necessary) until the seven sample items have been filled in correctly. Do not proceed with the test until the participant clearly understands the task. When the participant fills in a sample item correctly, offer encouragement by saying: "yes" or "right."

When the sample items have been completed successfully, say:

Script: "Yes, now you know how to do them." Spanish Script: *"Sí, ya sabe cómo hacerlo."* During the sample exercise, look to see if a left-handed participant blocks or partially blocks the key when filling in the marks. If this occurs, fold a separate template so that only the key is exposed and place it next to the participant's worksheet on the participant's right-hand side so that the extra key is aligned with the one blocked by the participant's left hand.

Have the participant use the separate key to complete the sample items and to take the actual test.

To begin the formal test, say:

Script: "When I tell you to start, you do the rest of them."

Spanish Script: "Cuando yo le diga que comience, haga el resto."

Point to the first test item and say:

Script: "Begin here and fill in as many squares as you can, one after the other, without skipping any. Keep working until I tell you to stop. Work as quickly as you can without making mistakes."

Spanish Script: "Comience aquí y llene tantos cuadros que usted pueda, uno detrás del otro sin saltarse ninguno. Siga haciéndolo hasta que le diga que pare. Hágalo tan rápido como pueda sin cometer ningún error."

Sweep across the first row with your finger and say,

Script: "When you finish this line, go on to this one."

Spanish Script: "Cuando termine esta línea, siga con esta otra."

And point to the first item in row 2.

Script: "Ready? Go ahead."

Spanish Script: ¿Listo? Comience."

Discretely begin timing.

Do not correct any incorrect symbols.

If the participant omits an item or starts to do only one type (e.g., only the "1"s) say,

Script: "Do them in order. Don't skip any."

Spanish Script: "Hágalos en orden. No salte ninguno."

Point to the first item omitted and say:

Script: "Do this one next."

Spanish Script: "Después, haga éste."

Do not correct additional omissions.

If the participant gets to the end of a line and stops, say:

Script: "Please go on to the next line."

Spanish Script: "Cuando termine esta línea, siga con esta otra."

Give no further assistance except (if necessary) to remind the participant to continue until instructed to stop.

The examiner must sit quietly and minimize movements to avoid distracting the participant during this test.

Timing must be precise. At the end of 90 seconds, say:

Script: "Stop. That's good, thank you. That completes this set of tasks."

Spanish Script: "Deténgase. Así está bien, gracias. Eso completa este conjunto de actividades."

2.3.1 Digit Symbol Substitution Test (Scoring and Discontinuation)

After the participant has left the room, the examiner scores the DSST. Record 1 point for each correctly drawn symbol completed within the 90-second time limit and record this number on the Cognitive Scoring Summary Form (Section B of the NEURO FORM).

A response is scored as correct if it is clearly identifiable as the keyed symbol, even if it is drawn imperfectly (e.g., "v" instead of "u") or if it is a spontaneous correction of an incorrect symbol.

Credit is not given for items completed out of sequence (e.g., doing all the 1's). Blank spaces between two completed items receive no credit.

If there is more than one symbol in the box, and one is correct, give the participant credit. The seven sample items are not included in the participant's score.

The DSST may be discontinued due to participant refusal, task difficulty (e.g., the participant never fully understood the instructions), or if the examiner determines that the participant is unable to perform the task due to a physical impairment such as a motor or visual problem.

If discontinued, the reason is recorded in Section B, item 3.a. of the Neurocognitive Scoring Summary Form (NEURO FORM).

3. QUALITY CONTROL ISSUES AND PROCEDURES

3.1. Training, Pre-certification, Certification and Recertification

A flowchart of the neurocognitive assessment training, pre-certification, and certification is included in the following page.

Prior to the first GRADE examination, examiners will train to a common level of proficiency in the administration and scoring of the neurocognitive measures. A training video can be obtained by emailing the Cognitive Coordinating Center.

One Master Tester per site, usually the main site study coordinator, was pre-certified at the Central Training meeting. New master testers will be pre-certified as necessary if there is staff turnover. The Cognitive coordinating center expects that candidates for certification will review training materials before training meetings so that central training activities are mostly limited to clarification of doubts rather than full training. We call the completion of central training and preliminary demonstration of proficiency *pre-certification*.

In order for testers to be pre-certified, they must demonstrate 80% proficiency in neurocognitive testing administered to a trainer from the Cognitive Coordinating Center at the central training meeting. Coordinators and examiners who meet criteria for pre-certification during the one-on-one sessions will be required to submit a copy of the Neurocognitive forms of the first participant tested to the Columbia University Cognitive Coordinating Center. If no significant errors are found they will be *certified* in administration of the neurocognitive testing. Alternatively, the one-on-one precertification can be conducted remotely via a web meeting using services such as skype.

Coordinators and examiners that are deemed to need further training after a one-on-one precertification session will be required to submit 1 audio-taped neurocognitive assessment on a nonparticipant. If this audio-taped assessment along with the scored cognitive form questionnaire meets criteria for pre-certification, examiners will be required to submit a copy of the scored cognitive forms of the first participant tested to the coordinating center in order to be certified.

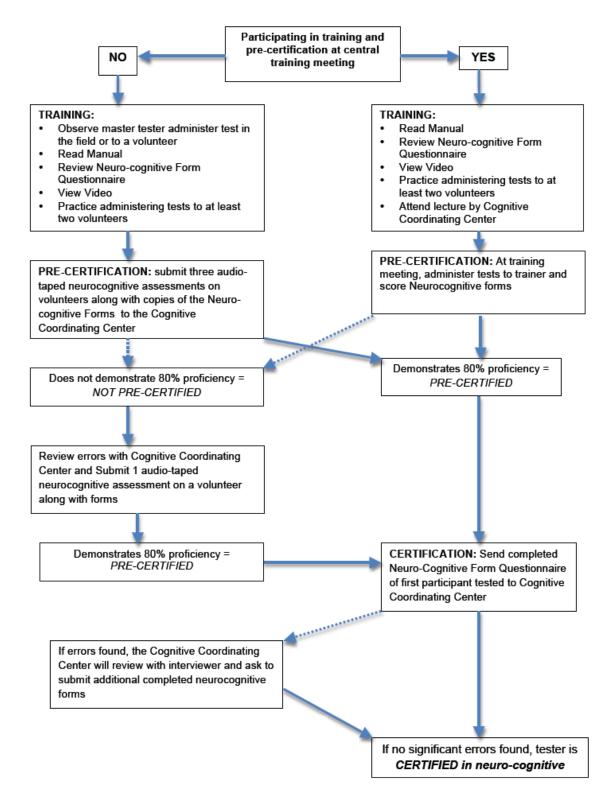
All new examiners will be trained by their site's master tester. In case the one-on-one precertification is not possible, the candidates will obtain approval from the field center master tester to submit three audio-taped neurocognitive assessments along with copies of the associated test forms to the Columbia University Cognitive Coordinating Center (CUCCC) for review for pre-certification. Pre-certification assessments are NOT to be performed on GRADE participants. Examiner pre-certification for the neurocognitive portion of the GRADE exam is achieved if no significant errors are found by the Cognitive Coordinating Center. Once pre-certified, certification will be achieved after review of the testing forms of the first GRADE participant assessed. Coordinators and examiners that are deemed to need further training will be required to submit 1 audio-taped neurocognitive assessment on a non-participant. If no significant errors are found on this audiotaped assessment along with the scored neurocognitive Form Questionnaire (NEURO FORM), the examiner will meet criteria for pre-certification.

Maintaining proficiency in the administration of the neurocognitive measures requires regular exposure to the protocol. In order to maintain certification, examiners should administer the cognitive assessments at least twice per month. These can be administered to a volunteer if it is not possible to

administer the cognitive tests to a participant at least twice a month, for a period of no longer than 12 months.

Repeat training for recertification will be necessary if there is a lapse in maintaining proficiency such as when there is a lapse in cognitive testing due to the study schedule (for example, if there is a one-year gap between waves of cognitive testing, even if practicing on volunteers). If waves of cognitive testing are conducted in such a way that there is no lapse in the administration of cognitive testing (e.g. there is no lapse between wave 1 and wave 2 of cognitive testing), training procedures for recertification as described above will not be necessary. In this case recertification will consist of submission of 1 form per tester for review at the cognitive coordinating center at the beginning of the new wave of cognitive testing. Testers will be recertified if they demonstrate proficiency following the criteria described above, similar to initial certification. If there is a lapse in cognitive testing (e.g. interval of 1 year or more), repeat training, pre-certification, and recertification will follow the guidelines described previously and will be performed in 3 possible scenarios: (1) one-on-one with a member of the CUCCC at scheduled training meetings; (2) one-on-one remotely with a member of the CUCCC, via web meetings (e.g. skype with video); or (3) by submission of audio recordings and testing forms for 3 volunteers to the CUCCC.

FLOWCHART OF NEURO-COGNITIVE ASSESSMENT TRAINING, PRECERTIFICATION, AND CERTIFICATION



3.1.1. Training, Pre-certification, Certification and Recertification in Spanish.

Only persons fluent in Spanish can be certified for the administration of the neurocognitive battery in Spanish. Procedures for training, pre-certification, and certification in the administration of the neurocognitive battery in Spanish are similar to those in English described above. If an interviewer is pre-certified in English, they only need to submit one taped assessment in Spanish on a volunteer to assess Spanish fluency. If an interviewer is not deemed to be fluent in Spanish on the audiotape they will not be pre-certified for administration of the cognitive battery in Spanish and may not be eligible for further training. Otherwise proficiency will be determined as for the English assessments. If an interviewer is not pre-certified for the administration of the neurocognitive battery in English, submission of 3 taped assessments on volunteers in Spanish are required along with scoring forms. Subsequent pre-certification and certification steps are similar to those for English assessments. Certification of neurocognitive assessment in Spanish will occur after submission of the forms of the first actual study participant interviewed in Spanish.

3.2 Quality Control

Copies of 10% of the cognitive assessment forms will be sent to the Columbia University Cognitive Coordinating Center. The Neurocognitive Form Questionnaire (NEURO FORM) will be reviewed to ensure accuracy of recorded responses and scoring.

Notes about any inconsistencies and errors will be sent to the field center lead examiner or study coordinator. Test score means and standard deviations are regularly tracked and reported for each, allowing detection of outliers and investigation of possible systematic differences by examiner.

Also, general feedback pertaining to all examiners is provided on regularly scheduled conference calls involving field center study coordinators. These calls also provide an opportunity to discuss and problem-solve any exam issues that arise.

Last, the site coordinators will conduct field observations to assess examiner performance and ensure an optimal testing environment.

A quality control report with statistics of errors found during quality control procedures will be generated on a quarterly basis or as required by the GRADE Coordinating Center.

3.3 General Training Guidelines for Site Coordinators/Lead Examiners.

The site coordinators/lead examiners will train new examiners with strict adherence to the following guidelines:

<u>1. Training.</u>

a. Coordinator/lead examiner will email the Cognitive Coordinating Center and the interviewer an acknowledgement that the interviewer's training has begun.

b. Interviewer reviews updated forms & manual.

c. Coordinator/lead examiner and interviewer will review forms/manual and answer any questions.

4. EXAMPLES OF FREQUENT QUESTIONS AND ANSWERS ABOUT COGNITIVE ASSESSMENTS.

The following are general scoring considerations that have come up during the quality control reviews

- 1. When scoring SEVLT please write the response type, either a C, R or I for each word.
- 2. When scoring Fluency tests, both Word and Animal, please circle or mark with an "X" the repetitions, perseverations and incorrect responses.

The following are examples of frequently asked questions (Q) and answers (A) that might help avoid errors.

4.1. GENERAL ADMINISTRATION Q & A'S

Q: I was administering the "Word Fluency" test this morning and as my participant was listing animals the intercom came on with a message. My participant tried to keep naming animals, but was definitely distracted and slowed down. Do I mark this test as being completed? If not, what do I put for "Why was it discontinued?" (the options are refusal, task difficulty, or impairment)? If yes, should I make a comment somewhere about this interruption?

A: Please count this test as complete. Also, write a comment on the form about what happened.

Q: Yesterday we had a participant whose first language is Spanish but is fluent in English. All of the previous questionnaires have been given in English. After the first round of the SEVLT he said he could remember things much better in Spanish. He did not do well. He did better on the word fluency tests and less well on the digit symbol task. I think he may have just felt anxious about being tested. We do not have a bilingual tester on staff. Should I make a comment on his form about this? A: The participant's native language being different than the language of administration may be a notable factor in the participant's performance. Please make a note on the form. *Rule: Administer the complete battery in the language and language tested previously. Do not switch language of administration from one task to the next.*

Q: I did a Cognitive Exam on a person today who is blind in one eye. She is able to see with glasses, but it is hard for her. I gave her the Digit Symbol sheet and asked her if she could see it and she said yes, so I answered the vision question as adequate. However, when she was doing the test, it did take her longer than other people to focus on the symbols. Is there anywhere I should note that this was true. I could put a comment into the data entry system but I'm not sure you would see that comment. A: Please rate vision as inadequate.

Rule: Rating of vision is subjective and it is based on what the participant says AND your observations while testing the participant. They should attempt each test and if they can't do it, explain why.

Q: My participant today had trifocals on. He does not wear separate reading glasses but commented that for a timed test and the lines in his glasses (3) he found his glasses a disadvantage. How do you want me to report his vision? Adequate or inadequate?

A: Although participant was wearing their glasses, their vision was impaired. Therefore their vision will be rated as inadequate.

Rule: Rating of vision is subjective and it is based on what the participant says AND your observations while testing the participant. They should attempt each test and if they can't do it, explain why.

Q: I was going to start my certification taping and realized our old cassette tape recorder is no longer functioning. However, we do have microcassette recorders here. Can I send a microcassette tape? A: Yes

Rule: Cassette, microcassettes, CDs, and electronic files (windows and apple compatible) are all acceptable.

Q: We wanted to know if we could give the subject some sort of acknowledgment of their efforts after each test. If so, what would be acceptable?

A: Yes. You can acknowledge by saying something about their efforts and not their actual performance. You can say "you are doing as well as anyone else who has taken this before." Also you can say "Just try your best."

Rule: The interviewer should provide general encouragement, and reassure each participant who asks that he/she did as well as others who have taken the tests

4.2. SPANISH ENGLISH VERBAL LEARNING TEST (SEVLT) Q & A'S

Q: I have a pt. that said "lentil" instead of ladle four times. I believe it was a true recall. The participant admitted to not knowing what a ladle was. Can I count that in the participant's favor?A: No - clinically important but research-wise it is not admissible. It is an intrusion.Rule: Do not correct any mispronunciations or errors. Write down exactly what the participant recalls.

Q: My participant today had excellent recall of words. In the 4th trial, she recalled 15 perfectly and then paused. She had time left and I was not 100% sure she had mentioned them all so I said, "Anything else?" She then began repeating words. Unless you tell me differently, I will not count the words that she said after she gave the complete list. She thought she had said them all but after my comment she kept going.

A: Please do not count the words as repetitions.

Rule: If the participant appeared to be self-cueing or going over what they had just said, do not score it as a repetition.

Q: On the SEVLT I gave the participant 30 seconds on the 1st and 2nd recall trials. I realized it at that point and repeated the list of words and allowed her 60 seconds for recall Trial 2. I then repeated the list another time (4th) giving her 60 seconds for recall Trial 3. So in the end, instead of hearing the list 3 times before the distraction list she heard it 4 times. She seemed to be finished on the first trial after 30 seconds so I don't think I really cut her off with the shorter time. Her first recall trial was counted. Her second recall trial was not counted. She was given another chance for 60 second recall Trial 2. Trial # 3 was done correctly but by then she had heard the list 4 times. I don't know if you can count this or if it needs to be thrown out. Let me know how you want to proceed.

A: Please count it do not throw it out.

Rule: If the participant was able to finish the test and all lists were administered, please score it and make a note on the form.

Q: I have a question about scoring the SEVLT. Often participants will say as they are remembering words: Did I say cabbage?...ladle?... Or I said cabbage, right? Or I know I said cabbage, peach, ladle...When posed as a question I have been recording it. I do not answer the question. I score it as a repeat b/c they seem not to know if they have said it. If they seem like they are just thinking out loud, "I said cabbage, ladle, juice..." I do not record it, b/c they seem to be doing a self-review. However, today

the pt. said to herself a few words she had said plus one she had not said. Previously she said pear and on her mini recall to herself she said peach. What is the correct way to handle these situations? A: These are not repetitions.

Rule: A repeat is only recorded if the person is saying the word again "as if" they never said it before. Give benefit of the doubt. Do not record and count as repetition if they are asking a question.

Q: I have noticed that pts begin to pluralize certain words, especially since beans and beets are plural. I had someone today say peach and then peaches later in trial 2 and 4. Please advise if I should mark this as an error or as an intrusion.

A: These are correct.

Rule: Plurals are correct responses.

Q: When I administer the assessment - the following occurs during the Spanish English Verbal learning Test (SEVLT): I have noticed that many of our volunteers "think out loud". You previously recommended that I not write the items on the scoring form that our participants were saying out loud - when they were "thinking out loud". To date, I have not done this. My issue is this... Sometimes when the volunteers are "thinking out loud" - they actually say a word that is on the recall list that they have not said during the current recall, but they think they have said it. (They may have mentioned it during a previous recall, but it has not been mentioned during the recall they are currently on).

So... How should I score this? Do I record the item - since it is on the recall list and it is verbalized to me? OR Do I not record the item - since it is mentioned to me as the person is "thinking out loud"? A: Write it and score as correct.

Rule: As long as they recall a word while "thinking out loud" the pt. should get the word scored correctly.

Q: if a patient misunderstands you and says beach instead of beets and you ask her about it and she misunderstood, can I count that as correct?

A: Count it as an intrusion. If the error persists write a note to us about this participant's assessment. *Rule: Do not correct any mispronunciations or errors, write down exactly what the participant recalls*

Q:What do you say to a patient who asks during the SEVLT "Have I already said beets?" A: "I am unable to tell you that. Anything else?"

Rule: **Do not indicate to the participant whether specific responses are correct or incorrect.**

Q: Is it ok on the SEVLT if a participant says green beans instead of beans? Is that a correct response? A: Green beans is an intrusion.

Rule: A response is classified as an intrusion error when the word is not on the target list.

Q: If a participant repeats a word, and then quickly says "I already said that", does it count as a repetition?

A: No.

Rule: if the participant acknowledges that they have already said a given word it does not count as a repetition. This is a way of self-cueing.

Q: If during the SEVLT they add a plural to the word "Pan" and say "pan" first try and pans on the 2^{nd} and 3^{rd} trials. Is that an intrusion or correct?

A: These are correct, not an intrusion.

Rule: Plurals are correct responses.

Q: One question related to the SEVLT is if the pt. says "news" instead of "newspaper", we assume that we score that response as an intrusion. However, we thought that we would just make sure. A: The word "news" would be an intrusion.

Rule: A response is classified as an intrusion error when the word is not on the target list.

4.3. LETTER FLUENCY Q & A's

Q: One of our participants responded "February" for the letter fluency assessment.

A: The word "February" is acceptable.

Rule: Words which are not capitalized but are not specifically names of persons or places will be counted as correct.

Q: I have a couple questions on participant answers for the neurocog test:

1.) For the f/p test: Is "funny" a repetition of "fun"?

2.) For the f/p test: Is February considered an incorrect response (and thus should not be counted towards the total)? It's not a place or a person, but it is always capitalized like a proper noun. A: Both acceptable.

Rule: If two words seem similar but are clearly separate words, give credit for both.

Q: Today my participant listed "fantastic" and then "fantasia" for the fluency test. Would these words be considered the same?

A: No, give both.

Rule: If two words seem similar but are clearly separate words, give credit for both

Q: A participant named "Facebook" as entry on the F/P test. Does this count as a proper noun (or place in cyberspace)? Should I count it as correct or incorrect?

A: Facebook is incorrect.

Rule: Words that are not capitalized but are not specifically names of persons or places will be counted as correct. Facebook is a name of a place on the Internet.

Q: Please review the following list, and tell me how to score it. After fire and free, are the rest of the words 'repeats'?

Fire Fry pan Freedom Firefly Firewood Fireplace Fry pan Frying

A. The first time the pt. said "Fry pan" is incorrect, the second "fry pan" is a repetition. Frying is correct. Freedom, firefly, firewood and fireplace are all different and/or distinct and are not repetitions.
Pulse If two words come similar but are clearly concerned a size and if for both

Rule: If two words seem similar but are clearly separate words, give credit for both

Q: We had a participant today who gave the word "fritz" during the Word Fluency Test. When I asked for clarification she said "not the name, you know like fritzing around or fritz your hair". While fritz is a word *GRADE Cognitive Manual Version 5/1/2021* Page 26

(-Verb phrase: fritz out, to become inoperable) it does not have the meaning the participant gave. So how would I count this word? Perseveration?A: The response is correct, not a perseveration.*Rule: Slang terms are admissible if in general use*

Q: Friend and friendship came up again. Fellow and fellowship?

A: Friend and friendship are considered the same word, fellow and fellowship are different words. *Rule: If two words seem similar, but they are clearly separate words, give credit for both. If two words seem similar because they are a simple derivation of the word, or the same word with an added suffix (e.g., -s, -ed, -ing, -ly), the second word should be considered a repetition*

Q: In the F word column there was the word "flown" and after it was the word "fly". The word fly was flagged as a repeat, I guess because it was considered a tense version of flown.

My question is: Could fly be considered OK because it could be the insect or the fishing hook, and not necessarily a tense version of flown? How would you know which the person meant?

A: Give the pt. the benefit and score them as two different words. Please accept as correct. *Rule: If the person provides two words that could mean different things, these are treated as two correct responses only when provided consecutively. If these words are spaced out with at least one word in between, the second instance must be scored as a repetition unless the person spontaneously indicates that they are referring to a different word.*

Q: I had a participant today who stated "phantom" during the Word Fluency portion of the test. I checked the word on <u>dictionary.com</u> and found that "fantom" is an acceptable spelling. How should this be scored? Also, for future cases, what should be our go-to reference to check questionable words? Is <u>dictionary.com</u> okay, for example.

A: "Fantom" is the archaic spelling and is not acceptable. You may use any reliable online dictionary as a source of reference.

Rule: Words are correct if they can be considered part of the English lexicon, the criterion being their listing in the standard translation of a dictionary.

Q: During the Word Fluency Test today, our participant said the following words in sequence: first, fifth, fifteen, fifty. How many points should she receive for this four word sequence?

A: These are all correct. Give all 4 points.

Rule: Numbers that are not a series are counted as correct.

Q: During the Word Fluency Test, I had a participant today who stated "fasting" and then 3 words later said "fast". It was not clarified which definition of "fast" he was referring to (i.e. fast running or to fast from food). Would this still be considered a repetition?

A: Yes, a repetition.

Rule: If the words are spaced out with at least one word in between, the second instance must be scored as a repetition unless the person spontaneously indicates that they are referring to a different word.

Q: How should I score these answers by a participant- "farm" and "farming"? "funk" and "funky" (participant said that he was referring to the same definition for funk and funky-I know fun and funny are considered different words since the definition of fun is independent of funny. Funky seems derivative/repetitive of funk in this case.). Participant also said "full" and "fully". Derivative/repetitive? A: These responses (farming, funky, fully) are all repetitions.

Rule: If two words seem similar, but they are clearly separate words, give credit for both. If two words seem similar because they are a simple derivation of the word, or the same word with an added suffix (e.g., -s, -ed, -ing, -ly), the second word should be considered a repetition.

Q: This morning during the "Word Fluency" test my participant listed the F words: "fee, fi, fo, fum" (from Jack and the Beanstalk). My guess is all are incorrect, but wanted to make sure.

A: Yes, all these are incorrect.

Rule: Words are correct if they can be considered part of the English lexicon, the criterion being their listing in the standard translation of a dictionary.

Q: During letter fluency assessment, pt. said "fly" followed immediately with "fly like to fly". Does this count as two words?

A: Yes, it does count as two words.

Rule: If the person provides two words that could mean different things, these are treated as two correct responses only when provided consecutively.

Q: On the F/P Word Fluency Test, the participant said "Friday" which is not a "name of a person or a place" so would I mark this correct? And then she said "facsimile" and then "fax" right after. Is this a repeat?

A: Friday is a correct response. Fax is a repetition of facsimile.

Rule: Words that are not capitalized but are not specifically names of persons or places will be counted as correct.

Q: I had a participant who said "fruit bowl, fruitcake, fruity" consecutively. Would any of these be considered as a repeat? May I have some more guidelines to help determine the difference between similar words that are "clearly separate words" versus "simple derivations of the same word"? I feel like verbs are more easily identified as repeats when they have different suffixes, but nouns and adjectives seem to be more difficult.

A: "fruit bowl, fruitcake, and fruity" responses are not considered a repetition. If they are considered different things and have different meanings, then they are not considered a repetition. *Rule: If two words seem similar but are clearly separate words, give credit for both.*

Q: During Word Fluency Test our participant said in sequence: fruit, fruitcake, fruit bat, later said flippant followed immediately by flip. Please clarify how to score.

A: Please score 'fruit', 'fruit cake' and 'fruit bat' as correct. 'Flippant' and 'flip' are both correct. *Rule: If two words seem similar but are clearly separate words, give credit for both.*

Q: I am not sure how to score a few of the items. The list of words given by the pt. is as follows: fox, for, from, forethought, fourth, fifth, five, fifteen, fortunate, from, fountain, fortune.

My questions are: do fourth and fifth constitute a "series" where only the first answer is correct? Are fifth and five considered a repetition?

Are fortunate and fortune similar enough to count as a repetition?

A: These all get a point. Fifth and five are not considered a repetition. Fifth denotes "placement" and five denotes "physical count of something". Fortunate and fortune would be counted as different for this test.

Rule: Numbers that are not a series are counted as correct.

Rule: If two words seem similar but are clearly separate words, give credit for both.

Q: Although these don't have different -ed, -en, -ing like endings we would like clarification: "friend & friendly, fun & funny, forth & forthright"

A: friend/friendly- same word, fun/funny- different words, forth/forthright-different words *Rule: If two words seem similar but are clearly separate words, give credit for both.*

Q: Can you please address the 2 similar but different words in Letter fluency: "fed" and "feed", "forget" and "forgotten." Are these considered the same word?

A: The words "fed" and "feed" are considered the same, a repetition, "forget" and "forgotten" are not the same, not a repetition.

Rule: If two words seem similar but are clearly separate words, give credit for both.

Q: In the Letter F/P test, the participant said 'free' and 'freedom' and 'final' and 'finality.' Can you tell us if the second words are repetition or correct?

A: Free and freedom are both acceptable, final and finality are not. Please score correctly whichever word they said first, final or finality. The second word is a repetition.

Rule: If two words seem similar but are clearly separate words, give credit for both.

4.4 ANIMAL FLUENCY Q & A's

Q: A participant started off the animal list with "jelly fish" and then "fish"; later she gave a series of other specific fish. Do I count the plain "fish" as an answer?

A: Yes, fish is correct. For example (bird, dog, etc.) and specific types (robin, terrier, etc.) are all correct when given during the 60 second trial.

Rule: Listing a species general name is acceptable as well as various types of a species are all acceptable.

Q. If the pt. says "fish" and then later on states various types (cod, trout, salmon, shrimp, etc.) of fish, would the word "fish" be considered a repetition? Also, same person stated Polar, Koala and Brown bears; would these be repetitions, too?

A: No, all correct.

Rule: Listing a species general name is acceptable as well as various types of a species are all acceptable.

Q: Under the animals section one of our pt. has answered the following, "bird, flamingo, robin, owl". Are these repetitions? If yes, which one should we count just bird or the latter 3? Other similar sounding answers are: Monkey, Orangutan, Baboon? Whale, shark, fish, eel? Do we take whale, shark, eel as correct answers and fish as repetition OR Fish as the answer and whale, shark, eel as repetitions? A: The responses are all correct and none are repetitions. A participant can give a species general name (for example, fish) and also give you types of fish and these would all be correct responses and not repetitions. The same goes for saying the word "bird" and naming types of birds, saying the word "dog" and naming types of dogs, etc. A repetition is made only when the participant says the exact same word again during the 60 second trial.

Rule: Listing a species general name is acceptable as well as various types of a species are all acceptable.

Q: On the animal section, a patient stated: seal and then for the next word seal lion. I looked the words up. There is a difference in their ears and feet. My question to you is that the same word?
A: That is right, they are different animals, same family. These responses are both correct.
Rule: Animals from the same family, defined as distinct animals are all acceptable.
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Q: Is hog considered a repetition of pig?A: Yes.*Rule: Animals from the same family, defined as distinct animals are all acceptable.*

Q: Today's participant is a 7th grade life science teacher and named a few difficult "animals" during the test. She mentioned "mollusks", "coelenterates", "protozoans" which are all classifications of animals. I was thinking this would be on the same lines as accepting "dog" or "bird" as a general classification, but I just wanted to make sure. She also said "amoeba", a single-celled organism. Would this, along with "protozoan" be accepted as "animals"? If "animal" is the simplified term for "organism", or even "moving organism", then I think they would count.

A: All responses are correct.

Rule: Listing a species general name is acceptable as well as various types of a species are all acceptable. Rule: Animals from the same family, defined as distinct animals are all acceptable.

Q: Also new today in animal category are: mammal; weevil & boll weevil. Does mammal count as an animal or is it not specific enough? Are weevil and boll weevil distinct enough to count as 2 animals? A: Mammal is not acceptable. One of the weevil is acceptable. They are not distinct enough to count as two.

Rule: Animals from the same family, defined, as distinct animals are all acceptable.

Q: Ok, we have an "ape," "gorilla" and "monkey" on a questionnaire today. I'm assuming "ape" is a repetition – is that correct?

A: These are all correct responses.

Rule: Listing a species general name is acceptable as well as various types of a species are all acceptable

Q: On the Animals section, pt. said "arthropods". Is this considered correct?

A: Arthropod is a correct response.

Rule: Listing a species general name is acceptable as well as various types of a species are all acceptable

Q: Is "person" acceptable for the animal category? A: Person is not acceptable for animal category.

Rule: For this test humans are not considered animals.

Q: When I did the Word Fluency Test (Animals). The participant understood the directions and named off a number of animals. Towards the end of her list - she named the following: Baby, Man, Woman, Child.

How would you code this?

A: None of these are correct responses. Rule: For this test humans are not considered animals.

Q: When stating names of animals, are insects ok? A: Yes, insects are correct.

Rule: Listing a species general name is acceptable as well as various types of a species are all acceptable

Q: Would the following answers would be a repetition: tadpole----frog, caterpillar---butterfly A: Either tadpole or frog, caterpillar or butterfly are repetitions if both forms (young/adult) are

mentioned during the 60 seconds. Please score the first response correct and the second response as a repetition.

Rule: Adult/young forms of an animal are both not acceptable within 60-second trial.

Q: For the animal recall test---can cat and kitten be counted as two correct answers? A: The word "kitten" is a repetition of "cat". *Rule: Adult/young forms of an animal are both not acceptable within 60-second trial.*

Q: In the word fluency animal category, the pt. responded "horse" and then "pony". I checked and basically a pony is a horse (meeting certain phys. requirements). Should it be scored as a repetition even though the pt. didn't use the same word or just as an incorrect response? The same type of scenario came up yesterday when a pt. responded "chicken" and then "rooster." I scored it as a repetition. Is that correct?

A: The second word for both are repetitions, "pony" and "rooster".

Rule: Adult/young forms of an animal are both not acceptable within 60-second trial. Rule: male and female of an animal are both not acceptable within 60-second trial.

Q: I have a quick question for scoring the animal category fluency. The pt. said: deer and fawn. (Since a fawn is a young deer I am not certain that I can count it).

A: Fawn is not accepted and is considered a repetition.

Rule: Adult/young forms of an animal are both not acceptable within 60 second trial.

Q: I have a question about the animal category of the word frequency test.

The participant responded #3 cat, then at #20 tomcat.

I would say tomcat is incorrect as the tomcat is just a male cat. Please advise.

Also, the participant stated #4 dog and then at # 21 wild dogs

I am thinking that may be a valid response as wild dogs are typically non-domestic and I believe that may be the formal name. Please respond as how I should grade this.

A: That is right, tomcat is incorrect and wild dogs is correct.

Rule: Animals from the same family, defined as distinct animals are all acceptable.

Q: On animal fluency pt. said "insect" and then starting saying all of the insects he could think of such as – "fly, mosquito, tick", etc. Do all count including insect?

A: Yes, they are all correct responses.

Rule: Listing a species general name is acceptable as well as various types of a species are all acceptable

Q: While listing animals, the pt. said "chicken" and then later said "rooster." The pt. also said "deer" and "antelope" and then later said "buck." I looked it up in the dictionary, and apparently "buck" can refer to the male of a deer, antelope, rabbit, sheep, or goat. I remember that the juvenile form of the animal and the adult form of the animal are considered the same, but what about male/female terms? A: Rooster is a repetition; buck is a repetition; male/female terms are repetitions. *Rule: Adult/young form of an animal are both not acceptable within 60 second trial.*

Rule: male and female of an animal are both not acceptable within 60 second trial.

Q: I was looking through the manual and found that your definition for a "perseveration" is "when the participant provides a response that is incorrect, but that would have been acceptable for a previous trial (e.g., providing "F" words during "ANIMAL" fluency). Perseverations are scored for the fluency trial

(i.e., "F" words) if the participant perseverates on the stimuli used (i.e. "T" words) in the example." However, all of us here have been counting any *incorrect* responses as perseverations. The manual says to *not *count incorrect responses at all (unless they are a perseveration).

A: This is correct. Do not continue to count all incorrect responses as perseverations. Count only those that meet criteria outlined in the manual.

Rule: A perseveration is scored when the participant provides a response that is incorrect, but that would have been acceptable for a previous trial (e.g., providing non-animal "F" words during "ANIMAL" fluency). Perseverations are scored for the 'F' fluency trial if the participant perseverates on the stimuli used (i.e. "T" words) in the example.

4.5 DIGIT SYMBOL Q & A's

Q. On the digit symbol test, a participant put marks that look like a cross between a V and a U (like a U with a pointed bottom) in the #5 boxes. Should these be counted as correct? A: This response is correct.

Rule: A response is scored as correct if it is clearly identifiable as the keyed symbol, even if it is drawn imperfectly (e.g., "v" instead of "u") or if it is a spontaneous correction of an incorrect symbol.

Q: On the digit symbol test: For a box with 2 in the top, the participant put a mark below it that looked like a minus sign with a distinctly present, but very small vertical line bisecting upward from it. The vertical line was not very tall in relationship to the length of the horizontal line. Should I still count it as correct since there is somewhat of a vertical line?

A: Yes, please count it as correct.

Rule: A response is scored as correct if it is clearly identifiable as the keyed symbol, even if it is drawn imperfectly.

Q: One of our pt. who is very fast and did excellent on the tests ended up writing the symbol for number 5 so fast that it looks like a capital U rather than the angular symbol it should be. How do I score this? Are these errors? He will have 7 errors if so and since 5 was not part of the sample test I was unable to catch it during the sample prep and no corrections are provided in sample script.

A: This happens very often with fast participants. These are not errors. No need to cue or correct the participant. This is fine.

Rule: A response is scored as correct if it is clearly identifiable as the keyed symbol, even if it is drawn imperfectly.

Q: A participant filled out #7 once correct with the proper symbol and then proceeded to fill in other #7 symbols as if it were "A" so they crossed midway with a line through the upside V. Shall I count these as errors even though they have an upside V but then added a slight line too? A: These are errors.

Rule: A response is scored as correct if it is clearly identifiable as the keyed symbol.

Q: I tested a pt. yesterday with Parkinson's. By the end of the test their hand was obviously getting tired. Some of their symbols were a little off, but as I was watching them I could tell they meant to extend the line little further but did not press down hard enough, or in another case extended the line a little too far. They did not correct the mistakes or maybe did not notice. Are these errors? A: No.

Rule: A response is scored as correct if it is clearly identifiable as the keyed symbol. GRADE Cognitive Manual Version 5/1/2021 Q: On the Digit Symbol test, if a participant skips a box and continues on and a staff person doesn't notice the skip so doesn't prompt the participant to fill in the empty space, how do we score that? My thinking is we would not count the skipped box but would count the boxes completed correctly after the skip. And then the staff person should be more careful about watching. Is that correct? A: Yes, that is correct.

Rule: Blank spaces between two completed items receive no credit.

Q: How do you score the Digit Symbol Test if a participant puts the triangle with the correct number but puts a line between the two bars of the "tent" of the V making it look like an A?A: This is an incorrect response and it would not get counted as correct.Rule: A response is scored as correct if it is clearly identifiable as the keyed symbol.

Q: I had a pt. who, on the Digit Symbol test, marked a cross mark across the ^ which made it look like an "A".

A: The digit symbol mark is incorrect.

Rule: A response is scored as correct if it is clearly identifiable as the keyed symbol.

Q: A participant was doing the digit-symbol test and marked a wrong symbol associated with a number; realized it themselves; and rather than erasing, the participant marked over the original incorrect symbol with the correct symbol before I could stop them. Should I count this response as wrong or allow the self-corrected response?

A: This response is correct.

Rule: A response is scored as correct if it is clearly identifiable as the keyed symbol, even if it is drawn imperfectly (e.g., "v" instead of "u") or if it is a spontaneous correction of an incorrect symbol.

5. ENGLISH AND SPANISH SCRIPTS FOR COGNITIVE ASSESSMENTS

5.1. English Scripts

ASSESSMENT A- SPANISH ENGLISH VERBAL LEARNING TEST (SEVLT) TIMED: ≤ 60 SECONDS

<u>TRIAL 1</u>

"First, I am going to read a list of words to you. I want you to listen carefully and try to remember the words as I read them. When I stop, I would like you to recall as many of the words as you can. You will not be able to remember all of the words so just do the best you can. You do not have to recall the words in the same order that I read them. Are you ready?"

"NOW TELL ME ALL OF THE WORDS YOU CAN REMEMBER"

"ANYTHING ELSE?"

<u>TRIAL 2</u>

"I am going to read the same list of words to you again. I want you to try to remember as many of the words as you can, including those you have recalled before. When I stop, I want you to recall as many of the words as you can remember."

"NOW TELL ME ALL OF THE WORDS YOU CAN REMEMBER"

"ANYTHING ELSE?"

TRIAL 3

"I will read the same list again. Listen carefully and when I finish tell me as many of the words as you can remember."

"NOW TELL ME ALL OF THE WORDS YOU CAN REMEMBER"

"ANYTHING ELSE?"

After trial 3, read the distracter list.

"I am going to read a different list of words. This time, I want you to repeat each word out loud after I read it."

"Now, I want you to tell me as many of the words from the <u>FIRST</u> list that I read as you can remember. That is the list that I read to you three times."

"ANYTHING ELSE?"

If they do not remember any words, prompt, "JUST GIVE IT A TRY" or "Take a moment to see if any of the words come to mind"

ASSESSMENT B- VERBAL FLUENCY TIMED: 60 SECONDS EACH

LETTER FLUENCY TIMED: 60 SECONDS

"On this next task, I will say a letter. Then I want you to tell me as many different words as you can think of, as fast as you can, that begin with that letter. There are only two exceptions. First, you may not say names of people and names of places. So, if I were to say "T," you could say words like 'table,' 'take,' or 'turtle' but could not say words like 'Thomas,' or 'Texas'.

"The second exception is that you may not say the same word with a different ending. For example, if you said 'take,' then you could not say 'takes,' or 'taking.' It's really the same word with different endings."

"Tell me as many words as you can that begin with the letter F. I will tell you when to stop. Go as quickly as you can. Ready, Begin!"

If no response after 5 seconds, say "Remember please tell me as many words as you can that begin with the letter F."

Prompts:

"Remember no names of people (places)."

"Remember not the same word with different ending."

"Remember, tell me words that begin with the letter F."

CATEGORY FLUENCY

TIMED: 60 SECONDS

"Now, I want to see how many different animals you can name. Any animals will do; they can be from the farm, the jungle, the ocean or house pets. They can begin with any letter. Go as quickly as you can. Ready. Begin!"

If no response after 5 seconds, say "Remember, please tell me as many animals as you can. They can begin with any letter."

Prompts:

"Can you think of any other animals?"

"Remember give me names of animals."

ASSESSMENT C- DIGIT SYMBOL TIMED: 90 SECONDS

"This last task is the digit-symbol task. Look at these boxes. Notice that each box has a number in the upper part and a special mark in the lower part. Each number has its own mark."

"Now, look down here to where the boxes have numbers in the top part, but the squares at the bottom are empty." POINT TO THE SAMPLE ITEMS.

"I want you to put in each of the empty squares the mark that should go there, like this."

"Here is a 2; the 2 has this mark. So I put it in this square, like this."

"Here is a 1; the 1 has this mark."

"So I put it in this square."

"This number is 3; the 3 has this mark."

"So I put it in this square."

"Now, you fill in the squares up to this heavy line."

"Yes, now you know how to do them."

TO BEGIN THE FORMAL TEST SAY: "When I tell you to start, you do the rest of them."

POINT TO THE FIRST TEST ITEM. "Begin here and fill in as many squares as you can, one after the other, without skipping any. Keep working until I tell you to stop. Work as quickly as you can without making mistakes.

"When you finish this line, go on to this one."

POINT TO THE FIRST ITEM IN ROW 2. "Ready? Go ahead." BEGIN TIMING.

AT THE END OF 90 SECONDS, SAY: "Stop. That's good, thank you. That completes this set of tasks."

PROMPTS:

"Do them in order. Don't skip any."

"Do this one next."

"Please go on to the next line."

"Please continue until I tell you to stop."

5.2. Spanish Scripts

ASSESSMENT A SPANISH ENGLISH VERBAL LEARNING TEST TIMED ≤60 SECONDS

TRIAL 1

"Primero, le voy a leer una lista de palabras. Quiero que escuche cuidadosamente y que trate de recordar las palabras a medida que las leo. Cuando me detenga, me gustaría que recordara tantas de las palabras como usted pueda. Tal vez, no podrá acordarse de todas las palabras, simplemente haga lo que usted más pueda. No tiene que recordar las palabras en el mismo orden que yo las leo. Listo (a)?"

"AHORA, DÍGAME TODAS LAS PALABRAS QUE USTED PUEDA RECORDAR."

"¿ALGUNA OTRA PALABRA?"

TRIAL 2

"Voy a leerle la lista de palabras de nuevo. Quiero que trate de recordar tantas de las palabras como pueda, incluyendo aquellas que recordó antes. Cuando me detenga, quiero que me diga tantas palabras como usted pueda recordar"

"AHORA, DÍGAME TODAS LAS PALABRAS QUE USTED PUEDA RECORDAR."

"¿ALGUNA OTRA PALABRA?"

TRIAL 3

"Voy a leer las mismas lista de palabras una vez más. Escuche cuidadosamente y cuando yo termine dígame tantas de las palabras como usted pueda recordar."

"AHORA, DÍGAME TODAS LAS PALABRAS QUE USTED PUEDA RECORDAR."

"¿ALGUNA OTRA PALABRA?"

AFTER TRIAL 3, READ THE DISTRACTER LIST

"Ahora, voy a leer una lista diferente de palabras. Esta vez, quiero que repita cada palabra en voz alta después de que yo la lea."

"Ahora, quiero que me diga todas las palabras de la <u>primera</u> lista que yo leí como usted pueda recordar, la que leí tres veces."

If do not remember any words, prompt- "Trate a ver si puede", o "Tome un momento a ver si alguna de las palabras le vienen a la mente."

ASSESSMENT B - VERBAL FLUENCY TIMED 60 SECONDS

LETTER FLUENCY

"En la siguiente actividad, voy a decir una letra y quiero que me diga, lo mas rápido posible, todas las palabras en las que pueda pensar que comiencen con esa letra. Solamente hay dos excepciones. Primero, no diga nombres de personas ni nombres de lugares. Por ejemplo, si yo dijera la letra "T," usted puede decir palabras como 'tabla', 'tomar' o 'tortuga' pero no puede decir palabras como 'Tomás', o 'Tijuana'."

"La segunda excepción es que no puede decir la misma palabra con diferente terminacion. Por ejemplo, si usted dice 'tomar', entonces no puede decir 'tomaron' o 'toman' porque es la misma palabra con diferente terminaciones."

"Dígame tantas palabras como pueda pensar que comiencen con la letra P. Yo le diré cuándo detenerse. Listo(a), empiece."

If there is no response after 5 seconds, say "Recuerde, dígame tantas palabras como pueda pensar que comiencen con la letra P."

Prompts:

"Recuerde, no diga nombres de personas (lugares)."

"Recuerde, no use la misma palabra con diferente terminación."

"Recuerde, dígame palabras que comiencen con la letra P."

CATEGORY FLUENCY

"Ahora, quiero ver cuántos animales diferentes usted puede nombrar. Cualquier animal esta bien; puede ser de la finca, de la selva, del océano u animales domésticos. Los nombres pueden comenzar con cualquier letra. Vaya lo mas rápido posible. Empiece."

If there is no response after 5 seconds, say "Recuerde, digame cuantos animales como usted pueda. Pueden comenzar con cualquier letra"

Prompts:

"¿Puede pensar en otros animales?"

"Recuerde, dígame nombres de animales."

ASSESSMENT C DIGIT SYMBOL

TIMED 90 SECONDS

"Esta última actividad es la actividad de dígitos-símbolos. Mire estas casillas. Note que cada casilla tiene un número en la parte de arriba y una marca especial en la parte de abajo. Cada número tiene su propia marca."

POINT TO THE SAMPLE ITEMS. *"Ahora, mire aquí abajo adonde los cuadros tienen números en la parte de arriba, pero los cuadros de abajo están vacíos."*

"Quiero que coloque la marca que debe ir en cada uno de los cuadros vacios."

"Aquí hay un 2; el 2 tiene esta marca. Entonces, lo coloco en este cuadro vacío, así"

"Aquí hay un 1; el 1 tiene esta marca".

"Entonces, lo coloco en este cuadro."

"Este número es el 3; el 3 tiene esta marca."

"Entonces, lo coloco en este cuadro."

"Ahora llene usted los cuadros hasta que llegue a esta línea gruesa."

WHEN THE SAMPLE EXERCISE HAS BEEN COMPLETED SUCCESSFULLY SAY: "Sí, ya sabe cómo hacerlo."

TO BEGIN THE FORMAL TEST SAY: "Cuando yo le diga que comience, haga el resto."

POINT TO THE FIRST TEST ITEM. "Comience aquí y llene tantos cuadros que usted pueda, uno detrás del otro sin saltarse ninguno. Siga haciéndolo hasta que le diga que pare. Hágalo tan rápido como pueda sin cometer ningún error."

"Cuando termine esta línea, siga con esta otra."

"¿Listo? Comience."

BEGIN TIMING.

Prompts:

"Hágalos en orden. No salte ninguno."

"Después, haga éste."

"Cuando termine esta línea, siga con esta otra."

AT THE END OF 90 SECONDS, SAY: "Deténgase. Así está bien, gracias. Eso completa este conjunto de actividades."