

cromis-2

Clinical Relevance Of Microbleeds In Stroke

**A guide to completing the
Case Report Forms (CRF)**

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Introduction

This booklet provides a guide for completing the Case Report Forms (CRFs) for both Study I (Atrial fibrillation-AF) and Study II (Intracerebral haemorrhage-ICH). It goes through the CRF of each study to highlight some important points not to be missed. Sections which are considered to be straight forward to be filled are not discussed.

In addition, for the Scales and Scores to be collected as part of the CRFs, a guide is provided for their administration and calculation.

Further information is available on the CROMIS-2 website: www.ucl.ac.uk/cromis-2.

Study I (AF)

Patient eligibility

Before a patient is entered into the study, the inclusion and exclusion criteria need to be checked. These criteria are explained in detail in the CROMIS-2 Researcher's Handbook.

a. Inclusion Criteria			
	Yes	No	
Has the patient presented with an ischaemic stroke or TIA within the last month?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Please tick the boxes as appropriate
Clinical diagnosis of atrial fibrillation (verified by ECG)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Intention to treat with anticoagulants (e.g. warfarin) by treating physician	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
MRI (including Gradient echo T2*) before or <1 week of starting anticoagulants	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

If any of the inclusion criteria listed above are checked “No”, the patient is NOT eligible for the study.

b. Exclusion Criteria	
MRI Contraindications	
	Yes No
Heart pacemaker	<input checked="" type="checkbox"/> <input type="checkbox"/>
Artificial (metallic) heart valve	<input checked="" type="checkbox"/> <input type="checkbox"/>
Pregnancy	<input checked="" type="checkbox"/> <input type="checkbox"/>
Metal plates	<input checked="" type="checkbox"/> <input type="checkbox"/>
Claustrophobia	<input checked="" type="checkbox"/> <input type="checkbox"/>
Unable to enter the MRI scanner	<input checked="" type="checkbox"/> <input type="checkbox"/>
Other MRI contraindication?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Clinical contra-indications	
Any known previous anticoagulant use (ever)	<input checked="" type="checkbox"/> <input type="checkbox"/>
Absolute contraindications to anticoagulant use (as decided by treating physician)	<input checked="" type="checkbox"/> <input type="checkbox"/>
Serious head injury ever (resulting in loss of consciousness)	<input checked="" type="checkbox"/> <input type="checkbox"/>

Please tick the boxes as appropriate

If any of the exclusion criteria listed above is checked “Yes”, the patient is NOT eligible for the study.

For all the patients not eligible to enrolled or excluded from the study please complete the CROMIS-2 eligibility screening log and keep in your site file. If a similar record is already kept as part of the Stroke Network activities, a copy of this should be kept in the site file, highlighting the patients screened for the study. The minimum information needed for these patients can be found in the following sample screening log.

Screening Log: CROMIS-2 Study I (AF)

Site:

Screening reference number	Date of Birth	Gender	Screening Date	NIH STROKE SCALE SCORE (/42) <small>(on admission to hospital or at clinic visit)</small>	Screening Status <small>(use codes below)</small>
□□□□	/ / mm/dd/yyyy	<input type="checkbox"/> M <input type="checkbox"/> F	/ / mm/dd/yyyy		
□□□□	/ / mm/dd/yyyy	<input type="checkbox"/> M <input type="checkbox"/> F	/ / mm/dd/yyyy		
□□□□	/ / mm/dd/yyyy	<input type="checkbox"/> M <input type="checkbox"/> F	/ / mm/dd/yyyy		
□□□□	/ / mm/dd/yyyy	<input type="checkbox"/> M <input type="checkbox"/> F	/ / mm/dd/yyyy		
□□□□	/ / mm/dd/yyyy	<input type="checkbox"/> M <input type="checkbox"/> F	/ / mm/dd/yyyy		

Sample Screen Status Codes:

- 1-Eligible
- 2-Eligible, declined participation
- 3-Not Eligible
- 4-Other, specify in space provided

Study II (ICH)

Patient eligibility

Before a patient is entered into the study, the inclusion and exclusion criteria need to be checked. These criteria are explained in detail in the CROMIS-2 Researcher’s Handbook.

The only inclusion criterion for Study II is patient to be presented with spontaneous ICH confirmed on neuroimaging (CT or MRI). Patients with ICH secondary to an underlying cause (e.g. trauma, tumour etc.) are excluded from this study, as well as patients with isolated intraventricular or subarachnoid haemorrhage, and haemorrhagic transformation of an infarct.

a. Inclusion Criteria	Yes	No	Please tick the boxes as appropriate										
Has the patient presented with symptoms compatible with stroke, and confirmed intracerebral haemorrhage (ICH, i.e. within the brain substance [parenchyma]) on neuroimaging?	<input type="checkbox"/>	<input checked="" type="checkbox"/>											
If yes, was it confirmed by brain imaging (MRI or CT) ?	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="width: 100%;"> <tr> <td colspan="2">If brain imaging was done, please tick</td> <td style="text-align: center;">Date</td> </tr> <tr> <td style="text-align: center;">CT</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">-- / -- / --</td> </tr> <tr> <td style="text-align: center;">MRI</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">-- / -- / --</td> </tr> </table>		If brain imaging was done, please tick		Date	CT	<input type="checkbox"/>	-- / -- / --	MRI	<input type="checkbox"/>	-- / -- / --
If brain imaging was done, please tick		Date											
CT	<input type="checkbox"/>	-- / -- / --											
MRI	<input type="checkbox"/>	-- / -- / --											
													

If any of the inclusion criteria listed above are checked “No”, the patient is NOT eligible for the study.

b. Exclusion Criteria		Yes	No
Age < 18 years	<input type="checkbox"/>	<input type="checkbox"/>	
Known underlying cause for ICH	<input type="checkbox"/>	<input type="checkbox"/>	
Trauma (recent head trauma sufficient to cause the ICH)	<input type="checkbox"/>	<input type="checkbox"/>	
-Tumour	<input type="checkbox"/>	<input type="checkbox"/>	
-Arteriovenous malformations	<input type="checkbox"/>	<input type="checkbox"/>	
-Clotting disorder	<input type="checkbox"/>	<input type="checkbox"/>	
-Drugs	<input type="checkbox"/>	<input type="checkbox"/>	
-Cerebral venous sinus thrombosis	<input type="checkbox"/>	<input type="checkbox"/>	
Isolated intraventricular haemorrhage (IVH)	<input type="checkbox"/>	<input type="checkbox"/>	
Isolated subarachnoid haemorrhage (SAH)	<input type="checkbox"/>	<input type="checkbox"/>	
Haemorrhagic transformation of infarct	<input type="checkbox"/>	<input type="checkbox"/>	

If any of the exclusion criteria listed above is checked “Yes”, the patient is NOT eligible for the study.

Table (c) in the Patient Eligibility section of the CRF (Table below), aims to identify patients taking oral anticoagulation at the time of the ICH – but please note that this is **not** either an inclusion or exclusion criterion.

c. Anticoagulation	Yes	No	U
Was the patient prescribed and known to be taking oral anticoagulation at the time of the ICH?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

For all the patients not eligible to enrolled or excluded from the study please complete the CROMIS-2 eligibility screening log and keep in your site file. If a similar record is kept as part of the Stroke Network activities, a copy should be kept in the site file, highlighting the patients screened for the study. The minimum information needed for these patients can be found in the following sample screening log.

Screening Log: Study II (ICH)

Site:

Screening reference number	Date of Birth	Gender	Screening Date	NIH STROKE SCALE SCORE (on admission to hospital or at clinic visit)	Glasgow Coma Scale (GCS)				Screening Status (use codes below)
					Total	Eyes	Motor	Verbal	
□□□□	/ / mm/dd/yyyy	<input type="checkbox"/> M <input type="checkbox"/> F	/ / mm/dd/yyyy						
□□□□	/ / mm/dd/yyyy	<input type="checkbox"/> M <input type="checkbox"/> F	/ / mm/dd/yyyy						
□□□□	/ / mm/dd/yyyy	<input type="checkbox"/> M <input type="checkbox"/> F	/ / mm/dd/yyyy						
□□□□	/ / mm/dd/yyyy	<input type="checkbox"/> M <input type="checkbox"/> F	/ / mm/dd/yyyy						
□□□□	/ / mm/dd/yyyy	<input type="checkbox"/> M <input type="checkbox"/> F	/ / mm/dd/yyyy						

Sample Screen Status Codes:

- 1-Eligible
- 2-Eligible, declined participation
- 3-Not Eligible
- 4-Other, specify in space provided

PREVIOUS EVENTS AND VASCULAR RISK FACTORS

The “Past Medical History” section is followed by a brief section regarding the previous history of ischaemic stroke, transient ischaemic attack (TIA) or intracerebral haemorrhage (ICH), which is relatively straight forward to be completed (see below).

History of previous ischaemic stroke, transient ischaemic attack (TIA) or intracerebral haemorrhage (ICH)											
Yes				No				Unknown			
	Y/N/U			Date of most recent event	Any other previous events of this type?		Date of first ever event of this type	Total number of previous events (ALL events of this type)			
	Y	N	U		Y	N					
Previous ischaemic stroke				__/__/____			__/__/____				
Previous TIAs				__/__/____			__/__/____				
Previous ICH				__/__/____			__/__/____				

This section should not be confused with the next questionnaire (see next page), which is about the history of transient neurological episodes *other than* transient ischaemic attacks (TIAs) which may have occurred prior to the ICH. Research suggests that such transient focal neurological episodes, with symptoms that are different to those of typical TIAs, can precede ICH in some patients. Most commonly, these attacks are described as paraesthesia (“pins and needles”). By contrast, TIAs generally cause a loss of neurological function, for example focal weakness or loss of sensation.

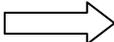
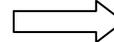
To elicit a possible history of these episode please ask both the patient patient and any relative/next of kin, and also check the medical notes.

History of transient focal neurological episodes

Research suggests that transient focal neurological episodes, with symptoms that are different to those of typical TIAs, can precede ICH in some patients. Most commonly, these attacks are described as paraesthesia (“pins and needles”). By contrast, TIAs generally cause a loss of neurological function, for example focal weakness or loss of sensation.

Can the participant (or a reliable informant, e.g. a relative or close friend) provide a reliable history	YES	NO
---	-----	----

If No, please STOP

	Yes	No	U																			
A. Paraesthesias																						
Q1: Episodes of paraesthesia (pins and needles, tingling)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If Yes  History of Paraesthesias-please tick all areas that were involved Please fill in: Y / N / U <table border="1"> <tr> <td></td> <td>Right</td> <td>Left</td> </tr> <tr> <td>Face</td> <td></td> <td></td> </tr> <tr> <td>Arm</td> <td></td> <td></td> </tr> <tr> <td>Hand</td> <td></td> <td></td> </tr> <tr> <td>Leg</td> <td></td> <td></td> </tr> <tr> <td>Trunk</td> <td></td> <td></td> </tr> </table>		Right	Left	Face			Arm			Hand			Leg			Trunk		
	Right	Left																				
Face																						
Arm																						
Hand																						
Leg																						
Trunk																						
Q2: If so, was the paraesthesia of a spreading onset (i.e. moving from one part of the body to another over time)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																			
Q3: Other associated symptoms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																			
Headache?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																			
Weakness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																			
Speech disturbance?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																			
Aphasia (altered content of speech)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																			
Dysarthria (slurred)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																			
B. Limb shaking																						
History of limb shaking episodes (or episodes of other abnormal movements)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If Yes  History of Limb shaking -please tick all areas that were involved Please fill in: Y / N / U <table border="1"> <tr> <td></td> <td>Right</td> <td>Left</td> </tr> <tr> <td>Arm</td> <td></td> <td></td> </tr> <tr> <td>Hand</td> <td></td> <td></td> </tr> <tr> <td>Leg</td> <td></td> <td></td> </tr> </table>		Right	Left	Arm			Hand			Leg								
	Right	Left																				
Arm																						
Hand																						
Leg																						
C. Visual disturbances																						
Q1: History of episodes involving visual symptoms?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																			
Q2: Were these typical of migraine? (zig-zags, flashing lights, distortions)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																			
Q3: Hallucinations (seeing things that are not there)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																			
If yes, these were (please tick):																						
-simple (e.g. blobs of colour)	<input type="checkbox"/>																					
-complex (e.g. formed objects)																						

For each type of attack reported (please circle Y, N or N/A)	Where these episodes all or mostly the same (stereotype)	Where these episodes multiple?	If so, how many (please circle)?	Date of first event?	Date of first event?	Duration of a typical attack

	d)?											
A. Paraesthesias	Y	N	N/A	Y	N	N/A	1	2-5	>10	--/--/--	--/--/--	... min ... hours ...days
B. Limb shaking	Y	N	N/A	Y	N	N/A	1	2-5	>10	--/--/--	--/--/--	... min ... hours ...days
C. Visual disturbances	Y	N	N/A	Y	N	N/A	1	2-5	>10	--/--/--	--/--/--	... min ... hours ...days

Was any action taken to treat these attacks?	Yes	No	U	Response to treatment (please tick)		
				Episodes diminished	No response	Response not known
<i>If yes, the action was to:</i>						
Stop antiplatelets	Yes	No	U			
Stop anticoagulation	Yes	No	U			
Start Anticonvulsants	Yes	No	U			

N/A = Not Applicable

Any other details of these episodes (please describe in as much detail as possible):

A detailed description of these attacks will be very useful when available.

For example:

"numbness and a tingling sensation around the corner of the mouth on the right (she is not sure whether the tongue is also involved); after 2-3 minutes the abnormal sensations spread to the right hand, over 1-2 minutes, without any obvious weakness.

Scales and Scores (Applies for both studies)

The scales and scores should be completed during patient's admission.

Scales and scores to be completed include:

- IQ-CODE (short version): *to be given to the patient's relative / carers / other informant to complete*
- MoCA (Montreal Cognitive Assessment): *to be administered to the patient by a research practitioner or other appropriate member of the research team*
- EQ-5D-5L: *to be given to the patient to complete*
- Modified Rankin Scale: *administered to the patient*

Please find below detailed instructions of how to complete each of these scales and scores

IQ-CODE

The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE; short version)

This assessment is directed at the patient's carer, family member or friend and is designed for them to complete. Generally, this test is completed without interference by a doctor or nurse, but it can be talked through with them if they need clarification.

Please give the questionnaire to patient's carer, family member or friend and ask them to follow the instructions for completing it.

How to calculate the final score of the test:

Scoring the test

1 = Much improved

2 = A bit improved

3 = Not much change

4 = A bit worse

5 = Much worse

	Score for this question
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	

Total score

To score the test, add up the result of each question (ie if 'Much improved' the result is 1 for that question), then divide this number by the total number of questions.

Record the final score of the test in the box below and also add this score to the patient's cognitive assessment record form.

Sum of the results of all of the questions

The total number of questions

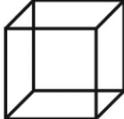
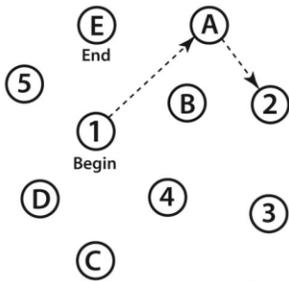
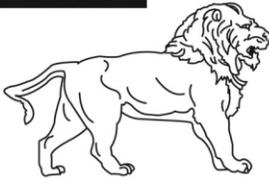
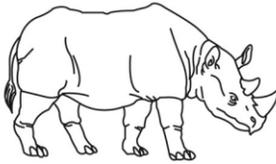
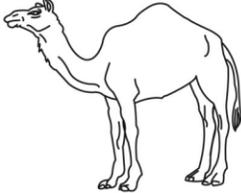
= _____ =

16

The final score should be filled to the corresponding section in the CRF.

MoCA (Montreal Cognitive Assessment)

The Montreal Cognitive Assessment (MoCA) was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. Time to administer the MoCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

MONTREAL COGNITIVE ASSESSMENT (MOCA) Version 7.1 Original Version		NAME : Education : Sex :	Date of birth : DATE :																			
VISUOSPATIAL / EXECUTIVE		Copy cube 	Draw CLOCK (Ten past eleven) (3 points)	POINTS																		
	[]	[]	[] [] []	___/5																		
NAMING					___/3																	
MEMORY		Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td></td> <td style="text-align: center;">FACE</td> <td style="text-align: center;">VELVET</td> <td style="text-align: center;">CHURCH</td> <td style="text-align: center;">DAISY</td> <td style="text-align: center;">RED</td> </tr> <tr> <td style="text-align: center;">1st trial</td> <td style="text-align: center;">[]</td> </tr> <tr> <td style="text-align: center;">2nd trial</td> <td style="text-align: center;">[]</td> </tr> </table>		FACE	VELVET	CHURCH	DAISY	RED	1st trial	[]	[]	[]	[]	[]	2nd trial	[]	[]	[]	[]	[]	No points
	FACE	VELVET	CHURCH	DAISY	RED																	
1st trial	[]	[]	[]	[]	[]																	
2nd trial	[]	[]	[]	[]	[]																	
ATTENTION		Read list of digits (1 digit/ sec.). Subject has to repeat them in the forward order [] 2 1 8 5 4 Subject has to repeat them in the backward order [] 7 4 2		___/2																		
ATTENTION		Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors [] FBACMNAAJKLBAFAKDEAAAJAMOF AAB		___/1																		
ATTENTION		Serial 7 subtraction starting at 100 [] 93 [] 86 [] 79 [] 72 [] 65 4 or 5 correct subtractions: 3 pts , 2 or 3 correct: 2 pts , 1 correct: 1 pt , 0 correct: 0 pt		___/3																		
LANGUAGE		Repeat : I only know that John is the one to help today. [] The cat always hid under the couch when dogs were in the room. []		___/2																		
LANGUAGE		Fluency / Name maximum number of words in one minute that begin with the letter F [] ____ (N ≥ 11 words)		___/1																		
ABSTRACTION		Similarity between e.g. banana - orange = fruit [] train - bicycle [] watch - ruler		___/2																		
DELAYED RECALL		Has to recall words WITH NO CUE	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">FACE</td> <td style="text-align: center;">VELVET</td> <td style="text-align: center;">CHURCH</td> <td style="text-align: center;">DAISY</td> <td style="text-align: center;">RED</td> </tr> <tr> <td style="text-align: center;">[]</td> </tr> </table>	FACE	VELVET	CHURCH	DAISY	RED	[]	[]	[]	[]	[]	Points for UNCUEDE recall only								
FACE	VELVET	CHURCH	DAISY	RED																		
[]	[]	[]	[]	[]																		
Optional		Category cue																				
Optional		Multiple choice cue																				
ORIENTATION		[] Date [] Month [] Year [] Day [] Place [] City		___/6																		
© Z.Nasreddine MD		www.mocatest.org		Normal ≥ 26 / 30																		
Administered by: _____		TOTAL		___/30																		
		Add 1 point if ≤ 12 yr edu																				

Administration and Scoring Instructions

1. Alternating Trail Making:

Administration: The examiner instructs the subject: *"Please draw a line, going from a number to a letter in ascending order. Begin here [point to (1)] and draw a line from 1 then to A then to 2 and so on. End here [point to (E)]."*

Scoring: Allocate one point if the subject successfully draws the following pattern:

1 -A- 2- B- 3- C- 4- D- 5- E, without drawing any lines that cross. Any error that is not immediately self-corrected earns a score of 0.

2. Visuoconstructional Skills (Cube):

Administration: The examiner gives the following instructions, pointing to the cube: *"Copy this drawing as accurately as you can, in the space below"*.

Scoring: One point is allocated for a correctly executed drawing.

- Drawing must be three-dimensional
- All lines are drawn
- No line is added
- Lines are relatively parallel and their length is similar (rectangular prisms are accepted)

A point is not assigned if any of the above-criteria are not met.

3. Visuoconstructional Skills (Clock):

Administration: Indicate the right third of the space and give the following instructions: *"Draw a clock. Put in all the numbers and set the time to 10 past 11"*.

Scoring: One point is allocated for each of the following three criteria:

- Contour (1 pt.): the clock face must be a circle with only minor distortion acceptable (e.g., slight imperfection on closing the circle);
- Numbers (1 pt.): all clock numbers must be present with no additional numbers; numbers must be in the correct order and placed in the approximate quadrants on the clock face; Roman numerals are acceptable; numbers can be placed outside the circle contour;

- Hands (1 pt.): there must be two hands jointly indicating the correct time; the hour hand must be clearly shorter than the minute hand; hands must be centred within the clock face with their junction close to the clock centre.

A point is not assigned for a given element if any of the above-criteria are not met.

4. Naming:

Administration: Beginning on the left, point to each figure and say: *“Tell me the name of this animal”*.

Scoring: One point each is given for the following responses: (1) lion (2) rhinoceros or rhino (3) camel or dromedary.

5. Memory:

Administration: The examiner reads a list of 5 words at a rate of one per second, giving the following instructions: *“This is a memory test. I am going to read a list of words that you will have to remember now and later on. Listen carefully. When I am through, tell me as many words as you can remember. It doesn’t matter in what order you say them”*.

Mark a check in the allocated space for each word the subject produces on this first trial. When the subject indicates that (s)he has finished (has recalled all words), or can recall no more words, read the list a second time with the following instructions: *“I am going to read the same list for a second time. Try to remember and tell me as many words as you can, including words you said the first time.”* Put a check in the allocated space for each word the subject recalls after the second trial.

At the end of the second trial, inform the subject that (s)he will be asked to recall these words again by saying, *“I will ask you to recall those words again at the end of the test.”*

Scoring: No points are given for Trials One and Two.

6. Attention:

Forward Digit Span: Administration: Give the following instruction: *“I am going to say some numbers and when I am through, repeat them to me exactly as I said them”*. Read the five number sequence at a rate of one digit per second.

Backward Digit Span: Administration: Give the following instruction: *“Now I am going to say some more numbers, but when I am through you must repeat them to me in the backwards order.”* Read the three number sequence at a rate of one digit per second.

Scoring: Allocate one point for each sequence correctly repeated, (N.B.: the correct response for the backwards trial is 2-4-7).

Vigilance: Administration: The examiner reads the list of letters at a rate of one per second, after giving the following instruction: *“I am going to read a sequence of letters. Every time I say the letter A, tap your hand once. If I say a different letter, do not tap your hand”*.

Scoring: Give one point if there is zero to one errors (an error is a tap on a wrong letter or a failure to tap on letter A).

Serial 7s: Administration: The examiner gives the following instruction: *“Now, I will ask you to count by subtracting seven from 100, and then, keep subtracting seven from your answer until I tell you to stop.”* Give this instruction twice if necessary.

Scoring: This item is scored out of 3 points. Give no (0) points for no correct subtractions, 1 point for one correction subtraction, 2 points for two-to-three correct subtractions, and 3 points if the participant successfully makes four or five correct subtractions. Count each correct subtraction of 7 beginning at 100. Each subtraction is evaluated independently; that is, if the participant responds with an incorrect number but continues to correctly subtract 7 from it, give a point for each correct subtraction. For example, a participant may respond “92 – 85 – 78 – 71 – 64” where the “92” is incorrect, but all subsequent numbers are subtracted correctly. This is one error and the item would be given a score of 3.

7. Sentence repetition:

Administration: The examiner gives the following instructions: *“I am going to read you a sentence. Repeat it after me, exactly as I say it [pause]: I only know that John is the one to help today.”* Following the response, say: *“Now I am going to read you another sentence. Repeat it after me, exactly as I say it [pause]: The cat always hid under the couch when dogs were in the room.”*

Scoring: Allocate 1 point for each sentence correctly repeated. Repetition must be exact. Be alert for errors that are omissions (e.g., omitting "only", "always") and substitutions/additions (e.g., "John is the one who helped today;" substituting "hides" for "hid", altering plurals, etc.).

8. Verbal fluency:

Administration: The examiner gives the following instruction: *“Tell me as many words as you can think of that begin with a certain letter of the alphabet that I will tell you in a moment. You can say any kind of word you want, except for proper nouns (like Bob or Boston), numbers, or words that begin with the same sound but have a different suffix, for example, love, lover, loving. I will tell you to stop after one minute. Are you ready? [Pause] Now, tell me as many words as you can think of that begin with the letter F. [time for 60 sec]. Stop.”*

Scoring: Allocate one point if the subject generates 11 words or more in 60 sec. Record the subject's response in the bottom or side margins.

9. Abstraction:

Administration: The examiner asks the subject to explain what each pair of words has in common, starting with the example: *“Tell me how an orange and a banana are alike”*. If the subject answers in a concrete manner, then say only one additional time: *“Tell me another way in which those items are alike”*. If the subject does not give the appropriate response (*fruit*), say, *“Yes, and they are also both fruit.”* Do not give any additional instructions or clarification. After the practice trial, say: *“Now, tell me how a train and a bicycle are alike”*. Following the response, administer the second trial, saying: *“Now tell me how a ruler and a watch are alike”*.

Do not give any additional instructions or prompts.

Scoring: Only the last two item pairs are scored. Give 1 point to each item pair correctly answered. The following responses are acceptable:

Train-bicycle = means of transportation, means of travelling, you take trips in both;

Ruler-watch = measuring instruments, used to measure.

The following responses are not acceptable: Train-bicycle = they have wheels; Rulerwatch = they have numbers.

10. Delayed recall:

Administration: The examiner gives the following instruction: *“I read some words to you earlier, which I asked you to remember. Tell me as many of those words as you can remember.”* Make a check mark (✓) for each of the words correctly recalled spontaneously without any cues, in the allocated space.

Scoring: Allocate 1 point for each word recalled freely without any cues.

Optional:

Following the delayed free recall trial, prompt the subject with the semantic category cue provided below for any word not recalled. Make a check mark (✓) in the allocated space if the subject remembered the word with the help of a category or multiple-choice cue. Prompt all non-recalled words in this manner. If the subject does not recall the word after the category cue, give him/her a multiple choice trial, using the following example instruction, *“Which of the following words do you think it was, NOSE, FACE, or HAND?”*

Use the following category and/or multiple-choice cues for each word, when appropriate:

FACE: category cue: part of the body multiple choice: nose, face, hand

VELVET: category cue: type of fabric multiple choice: denim, cotton, velvet

CHURCH: category cue: type of building multiple choice: church, school, hospital

DAISY: category cue: type of flower multiple choice: rose, daisy, tulip

RED: category cue: a colour multiple choice: red, blue, green

Scoring: No points are allocated for words recalled with a cue. A cue is used for clinical information purposes only and can give the test interpreter additional information about the type of memory disorder. For memory deficits due to retrieval failures, performance can be improved with a cue. For memory deficits due to encoding failures, performance does not improve with a cue.

II. Orientation:

Administration: The examiner gives the following instructions: “Tell me the date today”. If the subject does not give a complete answer, then prompt accordingly by saying: “Tell me the *[year, month, exact date, and day of the week]*.” Then say: “Now, tell me the name of this place, and which city it is in.”

Scoring: Give one point for each item correctly answered. The subject must tell the exact date and the exact place (name of hospital, clinic, office). No points are allocated if subject makes an error of one day for the day and date.

TOTAL SCORE: Sum all sub-scores listed on the right-hand side. Add one point for an individual who has 12 years or fewer of formal education, for a possible maximum of 30 points.

Quality of life: EQ-5D-5L

EQ-5D is a standardized instrument for use as a measure of health outcome. It is designed for self-completion by respondents

The EQ-5D self-report questionnaire (EQ-5D) essentially consists of two pages comprising the EQ-5D descriptive system (see below) and the EQ visual analogue scale (VAS).

Under each heading, please **tick the ONE box** that **best describes your health TODAY**

MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

COGNITION

- I am able to remember most things, think clearly, and solve day-to-day problems
- I am able to remember most things, but have a little difficulty when trying to think and solve day-to-day problems
- I am somewhat forgetful, but able to think clearly and solve day-to-day problems
- I am somewhat forgetful, and have a little difficulty when trying to think or solve day-to-day problems
- I am very forgetful, and have great difficulty when trying to think or solve day-to-day problems
- I am unable to remember anything at all, and unable to think/solve day-to-day problems

To score the descriptive system, a sequential scoring system should be used. For example, if the patient has ticked the responses like this:

MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

COGNITION

- I am able to remember most things, think clearly, and solve day-to-day problems
- I am able to remember most things, but have a little difficulty when trying to think and solve day-to-day problems
- I am somewhat forgetful, but able to think clearly and solve day-to-day problems
- I am somewhat forgetful, and have a little difficulty when trying to think or solve day-to-day problems
- I am very forgetful, and have great difficulty when trying to think or solve day-to-day problems
- I am unable to remember anything at all, and unable to think/solve day-to-day problems

The score would be 123451. Please insert this score into the CRF.

The patient's 'X' on the 0-100 scale should be recorded under 'visual analogue scale' out of 100.

Modified Rankin Scale

Modified Rankin Scale		Date: __ / __ / __
Total Score (0-6)	Estimated score before the current event	
	Score on discharge from hospital or clinic	

Score Description
0=No symptoms at all
1= No significant disability despite symptoms; able to carry out all usual duties and activities
2=Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3=Moderate disability; requiring some help, but able to walk without assistance
4=Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5=Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6=Dead