Title	Adaptation and Normalization of a Verbal Episodic Memory Test in French Sign Language
Acronym	RL-RI-LSF
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The Statistical Analysis Plan of the RL-RI-LSF Study

This Statistical Analysis Plan (SAP) was written according to the guidelines proposed by Yuan et al. [1].

1. SAP versions, dates and reasons for revision

Version #1: September 17th, 2026.

2. Trial registration number

NCT07726628 (Clinical trials Number)

ID-RCB 2024-A02627-40 (French Ethics Committee Number)

3. Study title

Adaptation and Normalization of a Verbal Episodic Memory Test in French Sign Language

4. Acronym

RL-RI-LSF

5. SAP contributors with roles and responsibilities

Camille ALLEYRAT (camille.alleyrat@chu-poitiers.fr): Methodologist, document writing.

Lisa DUROCHER (lisa.durocher@chu-poitiers.fr): Biostatistician, document writing.

Pierre-Alexandre BERARD (pierre-alexandre.berard@chu-poitiers.fr) : Coordinating investigator, document proofreading.

6. Background and rationale of study

While speech-language pathologists and psychologists specializing in neuropsychology have a wide range of tools at their disposal to assess the cognitive abilities of hearing adults, the tools available to them for evaluating deaf individuals who use French Sign Language (FSL) are far fewer: to date, we have only one adaptation of the Mini Mental State Examination (MMSE) by Fleurion et al. [2] for assessing overall cognitive function.

This gap stems from the perceptual, linguistic, and cultural differences inherent in sign language and limits the ability to provide care for deaf individuals with neurological conditions (stroke, neurodegenerative diseases, brain tumors). To date, no verbal tests—particularly those assessing verbal episodic memory—have been adapted for a deaf adult population, even though evaluating this cognitive domain can be critical for diagnostic purposes (for example, in the context of Alzheimer's disease).

In clinical practice, we use the RL-RI 16 episodic memory test because it is based on a cognitive view of memory and allows us to distinguish between the processes of encoding, storage, and strategic retrieval of verbal information. Unfortunately, like all French-language verbal memory tests, it is adapted and standardized for hearing individuals and does not allow for the assessment of verbal memory in deaf signers.

We propose conducting a two-phase study: first, we will adapt the RL-RI 16 test to French Sign Language (FSL). The resulting RL-RI-LSF test will then be standardized for the deaf population.

This statistical analysis plan pertains solely to the phase involving the standardization of the test for the deaf population (phase 2).

7. Study type

This is a prospective, multicentric, longitudinal trial.

8. Objectives and related endpoints (units and calculations used to derive outcomes)

8.1. Primary objective

The primary objective is to establish standardized data of the RL-RI-LSF test (RL-RI 16 episodic memory test adapted in FSL) for deaf subjects without cognitive impairment.

We will consider the following scores: immediate recall, entire set of free recalls (recall 1, 2, 3 and delayed recall), entire set of total recalls (recall 1, 2, 3 and delayed recall), and the recognition scores (number of words correctly recognized; number of accepted semantic distractors; number of accepted neutral distractors).

The recall scores correspond to the number of words correctly recalled by the subject for each recall.

8.2. Secondary objectives

The secondary objectives are:

- To evaluate the association between the RL-RI-LSF scores and the MMS-LS score.
- To assess the reliability (test/retest) of the RL-RI-LSF after 9 months.
- To expand the standardized data of the Rey-Osterrieth complex figure (ROCF) among deaf subjects without cognitive impairment, as a continuation of the work initiated by a team in Lille Hospital. The following scores will be considered: copy, immediate recall, delayed recall, recognition.
- To establish standardized data of 3 subtests of the WAIS-IV among deaf subjects without cognitive impairment. The following subtests will be considered: matrix reasoning, symbol search, coding.

9. Inclusion criteria

- Adult subject (≥ 18 years old).
- Subject with severe or profound deafness (hearing loss ≥ 70 decibels), early diagnosed (before 6 years old).
- Person whose main language is French Sign Language.
- Person affiliated to the French Healthcare system through self or another person.
- Person having given written consent after receiving clear and fair information.

10. Non-inclusion criteria

- Person with a medical history in neurology (stroke, traumatic brain injury, dementia) or psychiatry (bipolar syndrome or schizophrenia that would not be medicated, severe depression).
- Person with medical developmental background (e.g. genetic syndrome).
- Person with cancer history needing chemotherapy.
- Person with a diagnosed and untreated sleeping trouble.
- Person drinking > 10 glasses of alcohol per week or using drugs (except tobacco) on a daily basis.
- Person with visual issues not corrected.

- Vulnerable populations: minors, individuals deprived of liberty by judicial/administrative decision, adults under legal protection, patients in social/medical institutions.

11. Exclusion criteria (post-inclusion)

- Consent withdrawal.
- Insufficient MMS-LS score according to the schooling of the participant (MMS-LS ≤ 20/28 for participants with a degree, and MMS-LS ≤ 17/28 for participants without a degree).

12. Sample size calculation

Phase 2: 100 subjects.

For the standardization of the RL-RI-LSF test, the sample size is calculated using the equation N ≥ 50 + 8M proposed by Green [3], where N represents the sample size and M represents the number of independent variables (gender, age, and sociocultural level) in the linear model explaining the RL-RI-LSF score. According to this equation, the required number of deaf subjects is estimated at 74. To meet this requirement and allow for flexibility in case of patients with an exclusion criterion (pathological MMS-LS), we plan to include 100 deaf subjects.

13. Interim analysis (timing, person, adjustment of the significance level)

No interim analysis was planned.

14. Guidelines for an early stop of the study

The study may be prematurely suspended in the event of unexpected adverse events. On the same token, in the event of unexpected developments or new information and showing that the objectives of the study or the clinical program are unlikely to be reached, the sponsor may be persuaded to prematurely suspend the study.

No statistical discontinuation criteria have been drawn up.

15. Timing of the study

- Phase 2- Inclusion period: 12 months
- Phase 2- Subject participation duration: 9 months

16. Timing for assessing each collected parameter

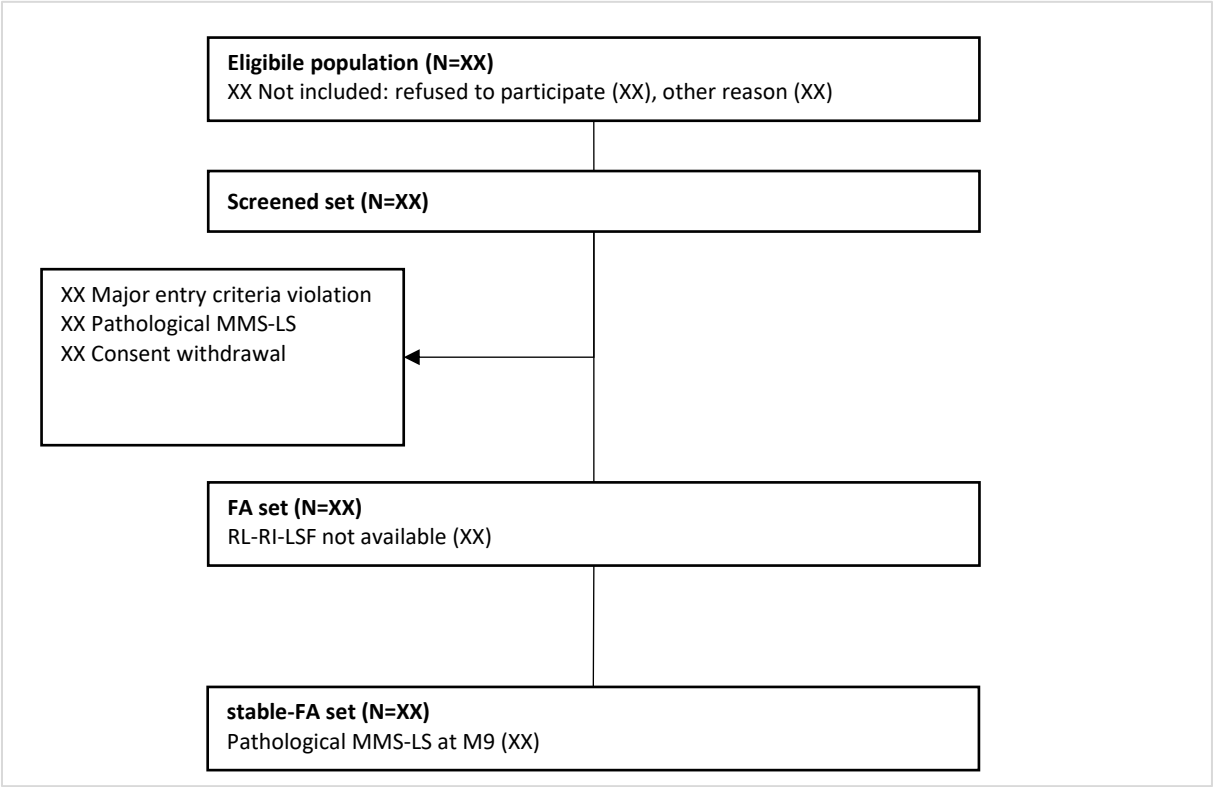
Phase 2	Inclusion (M0)	Follow-up (M9)
Information and eligibility	X	
Consent signature	X	
MMS-LS	X*	X
RL-RI-LSF (RL-RI 16 adapted in FSL)	X	X
Non-verbal interference tasks: Rey-Osterrieth complex figure, WAIS-IV	X	X

*Except for participants who took part in the Phase 1

17. Reporting the representativity of the studied population

A flowchart will be decomposed according to the following sets. The effectives and the related differences in-between two consecutive sets will be reported. The causes of the related differences will also be listed.

- The screened set. The participants who signed the informed consent.
- The full analysis (FA) set. The previous screened set, excluding participants who failed to meet major entry criteria (including subjects with a pathological MMS-LS at inclusion), participants who withdrew consent and participants without RL-RI-LSF available at inclusion.
- The stable full analysis (stable-FA) set. The previous FA set, excluding participants with a pathological MMS-LS at M9 (considered as subjects with a modified health state, see section 23).



18. Withdrawals and follow-up data

Patients may be withdrawn early from the clinical study for several reasons, including but not limited to consent withdrawal, exclusion criteria, lost to follow-up, death. The investigator will document the reasons for premature study discontinuation. The withdrawals will be exhaustively described in the flowchart.

19. Definition of the studied population

All the analyses will be performed based on the full analysis set, except for the test/retest analysis which will be performed on the stable full analysis set.

If a patient declines to give their consent, he/she will be asked for permission to use data obtained prior to withdrawal and to collect the primary outcome. If this is achieved, the patient will be included in the final analyses. If the patient declines, all data from that patient will be destroyed (except for safety data).

20. Level of statistical significance (p-values, confidence intervals, one- or two-sided)

For the primary and secondary objectives, statistical significances will be achieved for p-values < 5% by using two-sided alternative hypotheses and two-sided 95% confidence intervals.

21. Plan and rationale for controlling the type I error (multiplicity of tests)

We will not consider the inflation of the type I error. The level of the proof will be the higher for the primary outcome. The statistical analyses related the secondary outcomes will be consider as exploratory results with a risk of false positive.

22. Description of baseline patient characteristics

Demographic variables and other baseline characteristics will be summarized for the full analysis set. Missing data will be reported but no imputation will be performed.

The following quantitative data will be presented as means and standard deviation: age at inclusion (in years), age at onset of deafness (in months), MMS-LS score at inclusion (0-28). The following qualitative data will be presented as counts and percentages: gender (male; female), sociocultural background (with a degree; without a degree), handedness (left-handed; right-handed; ambidextrous; forced right-handed), dominant hand for signing (right; left; no dominant hand), onset of deafness (early; post-lingual; late), linguistic background (FSL; bilingual in FSL; FSL and spoken French), schooling in FSL (yes; no), native language (FSL; foreign sign language; French; foreign language), deaf family members who use sign language (yes; no), language used most frequently (FSL; French; equal proportion of FSL and French).

An additional table will present detailed characteristics regarding family background and history of deafness. The following data will be summarized using the mean and standard deviation or the number and percentage of participants in each category, depending on the distribution of the variable: family background (deaf participant with hearing parents; deaf participant with deaf parents; hearing child of deaf parents (CODA); hearing child of hearing parents (L2); deaf participant with foreign parents), educational background (mainstream school with hearing children; mainstream school with FSL; bilingual school (FSL and written French); specialized school with FSL; specialized oralist school), second language (yes; no), mother's highest level of education, father's highest level of education, mother's profile (deaf; hearing), father's profile (deaf; hearing), mother's native language (FSL; foreign sign language; French; foreign language), father's native language (FSL; foreign sign language; French; foreign language), language used to communicate with spouse (FSL; foreign sign language; French; foreign language), language used to communicate with children (FSL; foreign sign language; French; foreign language), language used with father (FSL; foreign sign language; French; foreign language), language used with the mother (FSL; foreign sign language; French; foreign language), language used with siblings (FSL; foreign sign language; French; foreign language).

23. Description of the outcomes

The outcomes of the participants will be summarized for the full analysis set. We expect a very low percentage of missing data on the outcomes. Missing data will be reported.

The mean and the standard deviation will be presented for the following quantitative outcomes: RL-RI-LSF scores at inclusion and at M9, MMS-LS score at inclusion and at M9, ROCF scores at inclusion and at M9, WAIS-IV scores at inclusions and at M9.

Floor and ceiling effects will be identified by analyzing the distribution of the RL-RI-LSF scores.

24. Statistical methods

The following analyses will be conducted using the FA set. Missing data will be described, but no imputation will be performed.

The RL-RI-LSF scores at M0 considered are as follows: immediate recall, 3 successive free recalls, 3 successive total recalls, 3 recognition scores (number of words correctly recognized, number of accepted semantic distractors, number of accepted neutral distractors), delayed free recall, and delayed total recall. Each score will be modeled using multivariate linear regression adjusting for age, sex, and sociocultural level. For each adjustment variable, we will present its effect on the score (regression coefficient). For scores that do not follow a normal distribution (skewed distributions, data with a floor/ceiling effect), we will report the percentiles (1, 5, 25, 50, 75, 95, 99) for each patient group stratified by age (18–49 years; 50–70 years; 70 years and older), sex (male or female), and sociocultural level (with or without a degree).

The correlation between each RL-RI-LSF score at M0 and the MMS-LS score at M0 will be assessed using Pearson's or Spearman's correlation coefficient, depending on the distribution of the scores. A correlation coefficient > 0.5 will be considered moderate, and a correlation coefficient > 0.7 will be considered high. The difference between the two tests will also be illustrated graphically using a correlation plot.

For each RL-RI-LSF score, test-retest reliability will be assessed using the intraclass correlation coefficient (ICC). The ICC will be calculated using a mixed-model ANOVA with two random factors (denoted as ICC(2,1) according to the convention established by Shrout and Fleiss [4]). An ICC > 0.75 will be considered good [5]. The participants included in this analysis will be those whose health status did not change significantly between M0 and M9—that is, the FA set with an MMS-LS score at M9 considered normal according to established norms, based on sociocultural level (see Section 11).

For the ROCF scores at M0 (copy, immediate recall, delayed recall, recognition) and the WAIS-IV scores at M0 (matrix reasoning, symbols search, coding) at M0, an age-adjusted linear regression will be performed. We will present the effect of age on each score (regression coefficient). For scores that do not follow a normal distribution, we will provide the percentiles (1, 5, 25, 50, 75, 95, 99) by age group.

25. References

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Annex #1: RL-RI 16

The RL-RI 16 test (16-item Free and Cued Recall in English) is used to assess verbal episodic memory [6].

Learning Phase

A list of 16 words is presented to the patient (4 words per card), belonging to 16 different categories (fish, clothing, fruit, vegetables, etc.). The patient must memorize them and is then asked to repeat the words from the list that they remember. The number of words correctly recalled during this immediate recall is tallied.

Next, three successive recall trials are administered. For each trial, the patient must first perform a free recall without assistance, followed by a cued recall in which the evaluator guides the patient by asking, for example, “What is the fish?” to remind them of the word “herring.” The total recall, which is the sum of the free and cued recalls, is also recorded.

Recognition Phase

Next, a recognition phase is conducted, in which the patient must recognize the words mixed in with semantic distractors (belonging to the same categories, such as “sardine” for “herring” or “hat” for “vest”) or neutral distractors (with no categorical or phonological relationship to the target words).

The number of correctly recognized words, the number of accepted semantic distractors, and the number of accepted neutral distractors are recorded.

Delayed Recall

Finally, a delayed free recall and a delayed cued recall are administered twenty minutes later to assess the long-term retention of the words. The total delayed recall is also calculated by adding the delayed free recall and the delayed cued recall.

Necessary Adaptations

The RL-RI-LSF procedure will be strictly the same regarding the order and timing of the recalls. To accommodate the specific needs of the deaf population, particularly a high illiteracy rate, the items will be presented in the form of signed language recorded on video.

Annex #2: MMS-LS

The MMS-LS is a cognitive screening test [7]. It is an adaptation of the Mini Mental State Examination designed for deaf patients who use sign language. The test takes about 5 minutes and provides a clinical assessment of language, memory, visuoconstructive abilities, and temporal-spatial orientation.

The total score is out of 28. A score of ≤ 20/28 for subjects with a degree or ≤ 17/28 for subjects without a degree is indicative of a possible cognitive impairment.

Annex #3: Rey-Osterrieth complex figure

The Rey-Osterrieth complex figure is a neuropsychological test. It involves copying an image composed of 18 specific elements [8].

First, there is a copying phase during which the clinician presents the model card horizontally to the examinee. The instructions are as follows: “Here is a drawing. You are going to copy it onto this sheet of paper. It doesn’t have to be an exact copy, but you should pay attention to the proportions and, above all, make sure not to leave anything out. There’s no need to rush.” The instruction is simple: “I’d like you to copy this drawing.”

Then there is a three-minute break. Next, the examinee is asked to “draw the same picture without the model”—this is the memory reproduction phase.

To calculate the accuracy score—for both the copy and the recall—the figure is divided into 18 elements. Each element is worth 4 points. The total possible score is therefore 72 points.

Annex #4: WAIS-IV

The Wechsler Adult Intelligence Scale, Fourth Edition (WAIS-IV), is a battery of tests used to assess adult cognitive functioning [9]. The test battery consists of 10 main subtests and 5 supplementary subtests. Here, we are particularly interested in the matrix reasoning, symbol search and coding subtests.

Matrix reasoning is a major subtest of the Perceptual Reasoning Index. The subject observes an incomplete matrix and selects the missing part from several possible answers. This subtest assesses fluid intelligence, general visuospatial intelligence, classification and spatial skills, knowledge of the relationships between the whole and its parts, simultaneous processes, and perceptual organization. The corresponding score ranges from 0 to 26.

Symbol search is a major subtest of the Processing Speed Index. Within a time limit, the subject observes a group of symbols and indicates whether one of these symbols belongs to the group of target symbols. In addition to processing speed, this subtest assesses short-term visual memory, visuomotor coordination, cognitive flexibility, psychomotor speed, operational speed, and attention. The corresponding score ranges from 0 to 60.

Coding is a main subtest of the Processing Speed Index. Using a code and within a time limit, the subject copies symbols paired with numbers. In addition to processing speed, this subtest assesses short-term visual memory, learning ability, psychomotor speed, visuomotor coordination, visual scanning ability, cognitive flexibility, and attention. The corresponding score ranges from 0 to 135.