RL-RI-LSF Study

Protocol summary

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French Research Ethics Committee Number	ID-RCB 2024-A02627-40 (initial approval: 24 March 2025)
Clinical Trials Number	NCT06902753
Title	Adaptation and Normalization of a Verbal Episodic Memory Test in French Sign Language
Sponsor	Poitiers University Hospital 2 rue de la Milétrie – CS 90577 86021 Poitiers Cedex, France
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Rationale	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, Folstein and McHugh, 1975) by Fleurion et al. (2020) 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 (Grober and Buschke, 1987; Van der Linden et al., 2004) 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.

Objectives	Primary objective 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. Secondary objectives 1) To assess the association between the RL-RI-LSF scores and the MMS-LS score. 2) To assess the reproducibility (test/retest) of the RL-RI-LSF after 9 months. 3) 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 the team in Lille Hospital. 4) To establish standardized data of 3 subtests of the WAIS-IV among deaf subjects without cognitive impairment.
Endpoints	Primary endpoint 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. Secondary endpoints 1) Correlation coefficient between the MMS-LS score and each score of the RL-RI-LSF. 2) Intraclass correlation coefficient for each RL-RI-LSF score, assessed at M0 and M9. 3) Scores of the ROCF considered: copy, immediate recall, delayed recall and recognition. 4) Subtests of the WAIS-IV considered: matrix reasoning, symbol search and coding.
Study design	Phase 1: single-centre study. Phase 2: multicentre, longitudinal study. The study will be conducted in two phases: • Phase 1: Adaptation of the RL-RI 16 test to French Sign Language (FSL). This phase will establish frequency-based lexical lists in FSL using categorical verbal fluency tasks on healthy, signing deaf participants. • Phase 2: Standardization of the RL-RI-LSF test, based on the lexical lists obtained in Phase 1. Phase 1 will be conducted with participants enrolled in the Poitiers University Hospital only. Phase 2 will be conducted in

	multiple centres, including Poitiers. Therefore, participants in Poitiers might be enrolled in the two phases. The two phases will be separated by a period of approximately 10 to 14 months to select the items that will make up the RL-RI-LSF test and to avoid any potential learning effect in participants who take part in both phases.
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.
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.
Exclusion criteria (post-inclusion)	- 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).
Strategies / Procedures	Phase 1: Adaptation of the RL-RI 16 test to FSL. <u>Inclusion visit</u> (1 hour): • Information and consent signature. • Assessment of cognitive performance using the MMS-LS* • Fluency task: the participant will be asked to provide as many signs as possible from different categories; for example, "in 1 minute, list as many signs as possible related to sports / vegetables / clothing…" **Participants with a MMS-LS score considered as pathological will be excluded (MMS-LS ≤ 20/28 for participants with a degree, and MMS-LS ≤ 17/28 for participants without a degree).*

	The goal of this phase 1 is to identify the most relevant semantic categories and signs. We will ultimately select 16 items to form the training set for the adapted RL-RI-LSF test, which will be standardized during phase 2. Phase 2: Standardization of the RL-RI-LSF test. Inclusion visit – M0 (1h30): • Information and consent signature. • Assessment of cognitive performance using the MMS-LS* (except for participants who took part in Phase 1). • Administration of the RL-RI-LSF. During the 20-minutes interval between the delayed recall and the subsequent recalls of the RL-RI-LSF, the following non-verbal interference tasks will be performed: ➢ Rey-Osterrieth complex figure. ➢ WAIS-IV (matrix reasoning, symbol search and coding). **Participants with a MMS-LS score considered as pathological will be excluded (MMS-LS ≤ 20/28 for participants with a degree, and MMS-LS ≤ 17/28 for participants without a degree).* Follow-up visit – M9 (1h30): • Assessment of cognitive performance using the MMS-LS. • Administration of the RL-RI-LSF. During the 20-minutes interval between the delayed recall and the subsequent recalls of the RL-RI-LSF, the following non-verbal interference tasks will be performed: ➢ Rey-Osterrieth complex figure. ➢ WAIS-IV (matrix reasoning, symbol search and coding).
Sample size	Phase 1: 30 subjects. Phase 2: 100 subjects. Participants can be included in both phases.
Study duration	Total study duration: 41 months Phase 1: Inclusion period: 8 months Patient participation duration: 1 hour Duration for the development of the test (including statistical analysis): up to 12 months Phase 2: Inclusion period: 12 months Patient participation duration: 9 months

Statistical analyses	Analyses for phase 1 For the development of RL-RI 16 test, words were selected based on their typicality, that is, according to their frequency. For statistical analysis, we will therefore establish a typicality ranking of the signs provided for each category of FSL fluency and select items based on their ranking. Depending on the richness of the data, we may also consider selecting words that are relatively well-known (mentioned by at least 30% of participants) but not too prototypical (mentioned by less than 70% of participants). Analyses for phase 2 Qualitative data will be presented as counts (percentages), and quantitative data will be presented as means (± standard deviation) or medians (1st quartile–3rd quartile). Analysis of the primary outcome: each score will be modelled using multivariate linear regression, adjusting for age, sex, and sociocultural level (with or without a degree). 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, sex, and sociocultural level. Analysis of secondary outcomes: the correlation between the RL-RI-LSF test at M0 and the MMS-LS at M0 will be assessed using Pearson's or Spearman's correlation coefficient, depending on the distribution of the scores. Test-retest reliability will be assessed using the intraclass correlation coefficient (ICC). The scores of the ROCF and the subtests of the WAIS-IV will be analysed in the same manner as the primary outcome; linear regression adjusted only with age or description of percentiles by age group if the distribution is not normal.
Monitoring of adverse events	For such a study, the monitoring of (serious or non-serious) adverse events (AE) according to the French Law is not mandatory. The AE are not collected according to the MedDRA (Medical Dictionary for Regulatory Activities).