Clinical Rehabilitation

The Italian version of the Erasmus MC modifications to the Nottingham Sensory Assessment (EmNSA-I) for patients following brain lesion: translation and reliability study.

Journal:	*Clinical Rehabilitation*
Manuscript ID	CRE-2021-11904
Manuscript Type:	Original Research Article
Date Submitted by the Author:	09-Nov-2021
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Keywords:	Brain injury, Stroke, Sensory assessment, Outcome measure, Somatosensory impairment

Abstract

Introduction: Sensory impairment is frequent following brain lesion, but no validated tool is available in Italian language for sensory assessment. The aim of this study is to develop the Italian version of the Erasmus MC modifications to the Nottingham Sensory Assessment (EmNSA-I) and investigate its internal consistency, intra-rater and inter-rater reliability.

Methods: All consecutive patients diagnosed with acquired brain injury or stroke were considered for inclusion in the study. The translation and cultural adaptation process was completed and the testing procedures of the EmNSA-I were standardized. Subsequently, internal consistency, intra-rater and inter-rater reliability of the EmNSA-I were investigated.

Results: A consecutive sample of 34 inpatients was enrolled. The internal consistency of the tactile sensations and the proprioception items of the EmNSA-I were generally acceptable to excellent with a range of Cronbach's alpha between 0.73 and 0.97. The intra-rater reliability of the tactile sensations and the proprioception items of the EmNSA-I were generally good to excellent with a range of weighted kappa coefficients between 0.47 and 1.00. Likewise, the inter-rater reliabilities of these items were predominantly good to excellent with a range of weighted kappa coefficients between 0.42 and 0.92.

Conclusion: The EmNSA-I is a reliable screening tool and the only one in the Italian language to evaluate primary somatosensory impairments in rehabilitation department inpatients with acquired brain injury or stroke. Further research is necessary to consolidate these results and establish the validity and responsiveness of the Italian version of the Erasmus MC modifications to the NSA.

Introduction

Acquired brain injuries often result in a loss of sensation. Sensory impairment seems to be present in at least 60% of stroke survivors.[1] No specific data report epidemiology and impact of sensory loss following traumatic brain injuries. Tactile sensation is normally more affected than proprioceptive sensation, with greater involvement of the upper limb compared to the lower limb.[2] Somatosensory function plays an important role in full motor impairment recovery and absence of sensory impairment was recorded in all patients with full motor recovery.[3] Sensation plays an important role in motor control during gait, responding to environmental and physiological conditions.[4] An alteration in sensory input is known to increase risk of falls.[5] In functional activities of the upper limb sensation correlates to timing and strength during reaching and grasping.[6] Independence in activities of daily living and participation is negatively influenced by impaired sensation.[2,7]

For these reasons, health professionals consider an evaluation of sensation key in the global assessment of patients in a clinical rehabilitation setting.[8] However, it is not always investigated thoroughly in clinical practice and a validated tool in the Italian language was not found in the literature. An appropriate tool in the assessment of patients following brain injury should be simple and fast to complete, non-ambiguous, and reliable both in terms of internal consistency and intra- and inter- rater reliability.[9]

The Nottingham Sensory Assessment (NSA) was first created in the UK in 1991,[10] revised by the same authors in 1998.[11] In 2006 a new revision of the scale was tested on patients with intracranial disorders of various etiology. This scale, Erasmus MC modifications to the (revised) Nottingham Sensory Assessment (EmNSA), showed good to excellent reliability.[12]

The EmNSA differs from other assessments of sensation available in the literature as it assesses all body parts and requires limited time and cost [12]. This study aims to translate the EmNSA in the Italian language and evaluate the reliability of the Italian version in terms of internal consistency and intra- and inter- rater reliability in patients with acquired brain injury or stroke.

Methods

The study took place at the rehabilitation department of the Ferrara University Hospital. The project was approved by the Ethical Committee of the Province of Ferrara (protocol n.32/2012) and follows the principles identified by the Helsinki declaration. Reporting of all process was conducted following STARD statement (Standards for Reporting of Diagnostic Accuracy Studies).[13] A STARD checklist is available as additional file.

Translation process

The translation and validation of the EmNSA in the Italian language was authorized by the authors of the original scale [12]. The translation process was carried out following the guidelines put forward by Sousa [14] and Baeza [15] and any doubts that emerged during the translation process were resolved through discussion and clarification with one of the authors of the original NSA and the EmNSA scales [14–16]. The EmNSA score sheet and the guidelines were translated from English into Italian by two independent bilingual translators. Consulting a third expert, an Italian native speaker, the discrepancies between the two translations were resolved and a Preliminary Initial Translated Version of the Instrument in the Target Language (PI-TL) was obtained, through a consensus process [14]. The PI-TL version was then translated into English by two independent English native speakers, who had no knowledge of the original version of the scale, obtaining two backward translations. A focus group formed by the four translators, the two physiotherapists and the medical doctor involved in the research, compared the two backward translations, the original version and the PI-TL, to develop a pre-final version of the instrument in Italian, the target language (P-FTL), obtaining conceptual, semantic and content equivalence [14]. In order to standardize the assessment a brief theoretical and practical training was carried out for the raters [17], who piloted the guidelines by assessing 5 patients. The data from these patients were not considered in the statistical analysis. This pilot study aimed to clarify the process, and following feedback received from the raters, through a consensus process, small changes to the graphic layout of the score sheet were made to

make it easier to use. The EmNSA score sheet included photos indicating the position of the therapists' hands during assessment of proprioception. These photos were kindly provided by the authors of the Original EmNSA scale. The final version was then used in the study to investigate its psychometric properties. Following the experimental phase the instrument's psychometric properties were analysed and a final EmNSA-I was obtained.

The reliability study

Participants

All consecutive patients, of 18 years or older, admitted to the rehabilitation department of the Ferrara University Hospital and diagnosed with acquired brain injury or stroke were considered for inclusion in the study.

Sampling was consecutive and non-probabilistic, seeking to include all patients. No time limits were set in terms of time since the acute event. Exclusion criteria were the presence of other neurological conditions that may affect sensory function, peripheral or spinal nerve injuries, diabetes, peripheral neuropathy, a score less than 5 in the Level of Cognitive Functioning (LCF) scale indicating that the assessment could not be completed reliably,[18] or a diagnosis of dysphasia when this meant the patient was not able to understand simple instructions, assessed with Aachen Aphasia Test.[19] Written informed consent was obtained from the patients. In order to guarantee anonymity, each patient was assigned a numeric code used in the study database.

The instrument

The EmNSA is a qualitative ordinal scale which assesses the loss of tactile and proprioceptive sensation in the upper and lower limb. For each item a score of 0 is assigned if no sensation is reported, 1 if sensation is partially impaired, 2 if sensation is intact. In the EmNSA guidelines, when a score of 2 for light touch is assigned for the whole limb, a score of 2 is assigned for all other tactile modalities of that limb. In this study, all tactile modalities were assessed, independent from the score obtained

for light touch, in order to allow for a comprehensive analysis of the data. The equipment needed to assess tactile sensation consists of a cotton wool ball and a toothpick.

Procedure

All patients admitted to the rehabilitation department of the University hospital of Ferrara who met the inclusion criteria were assessed by two physiotherapists, Rater A (10 years of experience) and Rater B (23 years of experience). The assessment took place in a comfortable and quiet environment. Every patient was assessed in the supine lying position, with forearms supinated. The patients were requested to close their eyes during the assessment. Any clothing was removed from the tested part, while respecting the patient's dignity. The stimuli for tactile sensation were administered on each limb, starting distally, using the predefined points of contact in the following order: light touch (LT), pressure (PR), pinprick (PP), sharp/blunt discrimination (S/B). These stimuli were provided with cotton wool ball (light touch), the rater's index finger (pressure), and toothpick (pinprick). Proprioceptive sensation was tested by mobilising the body parts from distal to proximal. There was an interval of 1-2 hours between assessments by Rater A and Rater B. A re-test was completed by Rater A after 24-72 hours. Each rater did not have access to the assessment completed by the other.

Statistical analysis

Assessment of intra- and inter-rater reliability was carried out using weighted kappa coefficient (κw).[20] The κw was used in its quadratic formula.[21] The scores obtained were categorized following Fleiss's classification.[22] A confidence interval of 95% was established to guarantee an acceptable level of accuracy.[23] Homogeneity of the scale's items was defined by Cronbach's Alpha Index, following the categorization suggested by De Vellis.[24] The statistical analysis was carried out on the data referring to the affected side or the most affected side in the case of bilateral somatosensory impairment. This was chosen based on total scores across all sensory modalities and body areas. The descriptive analysis and internal consistency analysis was carried out with the statistical software

IBM SPSS Statistics v19.0.0 (IBM Company); the agreement analysis was carried out with the statistical software MedCalc v12.3.0 (MedCalc Software).

Results

A total of 44 patients who met the inclusion criteria were admitted to the rehabilitation department. The final cohort comprised 34 patients, as 10 were discharged before the assessments could be completed.

The mean (SD) age was 54 (17). The characteristics of the total sample are summarized in Table 1. Dysphasia affected 9% (n=3) of the study group and was such that the patients were able to take part in the study. The severity of sensory deficit was classified following the same system used in the original EmNSA study [12], and 40% of the sample demonstrating severely impaired sensation, 30% slightly impaired and 30% normal sensation.

[INSERT TABLE 1 ABOUT HERE]

Internal consistency for all the tactile sensations was excellent. For proprioception, excellent internal consistency was found for the upper limb, but this was only at an acceptable level for the lower limb (Table 2). For the intra-rater reliability analysis the weighted kappa coefficient values were predominantly excellent (range 0.84 – 0.98) with only 5 (12,5%) of the 40 results showing a moderate agreement (Figure 1a). Weighted Kappa coefficient values for inter-rater reliabilities were excellent for 21 (52,5) of the 40 values calculated, with 15 (37,5%) values classified as good and 4 (10%) as moderate (Figure 1b). No adverse effects were recorded during testing procedures.

[INSERT TABLE 2 ABOUT HERE]

[INSERT TABLE 3 ABOUT HERE]

[INSERT TABLE 4 ABOUT HERE]

[INSERT FIGURE 1 ABOUT HERE]

Discussion

The Italian version of the "Erasmus MC modifications to the (revised) Nottingham Sensory Assessment" (EmNSA-I) demonstrated, both for tactile and proprioceptive sensation an intra- and inter-rater reliability predominantly good to excellent. Furthermore, the internal consistency results contribute to confirming the EmNSA-I as a scale with good reliability, which justifies its use in clinical practice.

The results of the study support the use of the Italian translation of the scoresheet and guidelines, to include the photographs provided by the authors of the EmNSA which, from feedback received by the raters, aid the interpretation of the guidelines for proprioception.

No major differences were found comparing different level of sensory loss present in the two samples. In this study, 30% of patients had no sensory loss, 70% had sensory loss, (29% slight and 41% severe). The original EmNSA was conducted on a sample of patients where 28% had no sensory loss, 72% had sensory loss, (slight in 33% and severe in 39%).

Comparing this study with the original reliability study for EmNSA, considering the total scores across all items and modalities, similarly to the original scale, the results are mainly good to excellent, with no poor agreement (Table 3, 4). In both studies intra-rater reliability, as expected, was higher than inter-rater reliability across all modalities.

The lower agreement in the inter-rater reliability observed in the EmNSA-I could probably be due to the different sample recruited for the assessment. The Italian sample included a higher number of patients following TBI who tend to have a greater increase in muscle tone than stroke patients, making the assessment of proprioception more difficult. Furthermore, the raters' different level of experience could contribute to this discrepancy. Both versions show less reliability in the assessment of the lower limb compared to the upper limb, which may be explained by considering their different cortical representation. This result could also be related to the fact that in the stroke population the upper limb is more affected than the lower limb [2]. Furthermore, the lower agreement found may in part depend on the reliability of the method of testing as the lower agreement found in the lower limb in the

assessment of proprioception could be related to the lower limb generally being heavier, which can make the assessment more challenging for the therapist due to difficulties in handling the limb.

The lower agreement found for pinprick compared to light touch and pressure leads to a few observations. In the original study, pinprick is considered a tactile stimulus, however it is possible that when applying the stimulus with a toothpick, nociceptors are activated, due to the reduced surface stimulated [25]. This result can be interpreted as indicating that pinprick could be considered as a pain rather than tactile sensation. In compiling the final version of the guidelines, these observations led to modify the criteria for assigning score for tactile sensation. In this final version the pinprick test is carried out even if the patient has obtained a score of 2 in light touch. For the sharp/blunt discrimination the patient must have a score of 2 in light touch, pressure and pin prick. The interpretation of the sharp/blunt discrimination item is also open to further discussion. A deeper analysis exploring what kind of information this test is providing would be useful in interpreting the clinical findings. Moreover, following brain injury some patients are likely to have difficulties comparing two different stimuli as this is a more cognitively demanding task.

Evaluating the Italian scale in light of the criteria identified by Connell in her systematic review on sensory assessment [26], the time needed to complete the test is 10-15 min, the same as for EmNSA, the materials are easily available and the cost is negligible. Following the principles set out by Stolk-Hornsveld et al. [12] the inclusion criteria are representative of patients with acquired brain injury or stroke who are admitted to hospital for neurological rehabilitation in Italy, further justifying the use of the EmNSA-I in the clinical context. The raters, working within the rehabilitation unit, were is some cases aware of the patient's medical history, which constitutes a limitation of this study. Moreover, the intra-rater reliability data was obtained from one rater only, therefore a further analysis of intra-rater reliability by at least two raters with different levels of experience is recommended.

Conclusion

Sensory function plays an important role in daily activities and following acquired brain lesion loss of sensation is frequent. Despite this, sensory deficits are not always investigated thoroughly in clinical practice and no validated and reliable tool is available for the assessment of somatosensory impairment for Italian health professionals. The aim of this study was therefore to present the validation in Italian of the EmNSA scale. The EmNSA-I is a standardised reliable assessment scale that can be completed rapidly and simply and does not need specific or expensive equipment. It is the only sensory assessment scale for patients with acquired brain injury or stroke available in Italian.

Clinical messages

- Sensory impairment is frequent following brain lesion
- No Italian tools were present for sensory assessment
- The EmNSA-I is a standardised reliable assessment scale
- Further studies needed to confirm our results

Acknowledgments

This project was completed thanks to close collaboration with the Rehabilitation Department at the University of Ferrara. We would like to thank the translators Carlo Perrone, Lucio Marcello, Maddalena Amadori.

Author Contributions

AB, GB, EM, SL, JLC and NB conceived the study and participated in its design. AB, GB and EM performed clinical data collections. AB and SS analysed the data. AB, SL and SS interpreted the results. AB, SL and SS drafted and revised the manuscript. All authors approved the submitted version.

Competing Interests

No potential conflict of interest was reported by the authors.

Funding support

The authors received no financial support for the research, authorship, and/or publication of this article.

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Table 1. Characteristics of the sample

	Frequency (%) Total (34)
Gender	
Male	21 (62)
Female	13 (38)
Acquired brain injury	
Haemorrhagic stroke	15 (45)
Ischemic stroke	7 (20)
Traumatic brain injury	7 (20)
Subarachnoid haemorrhage	2 (6)
Brain tumour	2 (6)
Brain lobectomy	1 (3)
Side affected	
Left	12 (36)
Right	11 (32)
Bilateral	11 (32)
Side assessed	
Left	16 (47)
Right	18 (53)
Sensory impairment [a]	
Severe	14 (40)
Slight	10 (30)
Absent	10 (30)

[a] severe: absent or impaired sensory function in five or more test item; slight: absent or impaired sensory function in less than five test item; absent: normal sensory function in every test item.

Table 2. Cronbach's alpha values for the internal consistency of the EmNSA-I

	Light touch	Pressure	Pinprick	Sharp-blunt discrimination	Proprioception
Upper limb	0.97	0.96	0.93	0.96	0.95
Lower limb	0.97	0.96	0.91	0.93	0.73

Table 3. Comparison of weighted kappa values for the intra-rater reliability between EmNSA-I and EmNSA (Rater A)

	Light touch		Pressure		Pinprick		Sharp/blunt discrimination			Proprioception	
	EmNSA-I	EmNSA	EmNSA-I	EmNSA	EmNSA-I	EmNSA	EmNSA-I	EmNSA		EmNSA-I	EmNSA
Fingers	0.81	0.62	0.78	0.87	0.54	0.87	0.74	1.00	Fingers	0.92	1.00
Hand	0.80	0.71	0.83	0.63	0.56	0.87	0.91	0.71	Wrist	0.61	0.63
Forearm	0.89	1.00	0.92	1.00	0.77	1.00	0.86	1.00	Elbow	0.91	1.00
Upper arm	0.77	0.84	0.85	0.84	0.76	1.00	0.72	1.00	Shoulder	0.90	[a]
Upper limb	0.83	0.83	0.87	0.89	0.75	0.91	0.91	0.83	Upper limb	0.90	0.84
Toes	0.89	0.86	0.83	0.75	0.65	0.79	0.69	0.58	Toes	0.68	0.85
Foot	0.82	0.76	0.84	0.92	0.59	1.00	0.74	0.82	Ankle	0.65	1.00
Leg	0.82	0.81	0.90	0.91	0.73	0.89	0.78	0.69	Knee	0.64	1.00
Thigh	0.81	1.00	0.66	1.00	0.68	0.87	0.72	0.71	Hip	0.64	1.00
Lower limb	0.87	0.77	0.88	0.83	0.75	0.87	0.81	0.71	Lower limb	0.42	0.91

[a] Kappa value could not be calculated

Table 4. Comparison of weighted kappa values for the inter-rater reliability between EmNSA-I and EmNSA

	Light touch		Pressure		Pinprick		Sharp/blunt discrimination			Proprioception	
	EmNSA-I	EmNSA	EmNSA-I	EmNSA	EmNSA-I	EmNSA	EmNSA-I	EmNSA		EmNSA-I	EmNSA
Fingers	0.81	0.89	0.78	1.00	0.54	0.87	0.74	1.00	Fingers	0.92	0.71
Hand	0.80	0.87	0.83	1.00	0.56	0.76	0.91	0.84	Wrist	0.61	0.63
Forearm	0.89	0.87	0.92	1.00	0.77	1.00	0.86	0.84	Elbow	0.91	1.00
Upper arm	0.77	0.71	0.85	0.84	0.76	1.00	0.72	1.00	Shoulder	0.90	0.46
Upper limb	0.83	0.90	0.87	1.00	0.75	0.88	0.91	0.86	Upper limb	0.90	0.74
Toes	0.89	0.86	0.83	0.83	0.65	0.90	0.69	0.53	Toes	0.68	0.69
Foot	0.82	0.85	0.84	0.92	0.59	0.90	0.74	0.81	Ankle	0.65	[a]
Leg	0.82	0.83	0.90	0.83	0.73	0.79	0.78	0.90	Knee	0.64	1.00
Thigh	0.81	0.89	0.66	0.90	0.68	0.79	0.72	0.61	Hip	0.64	1.00
Lower limb	0.87	0.81	0.88	0.83	0.75	0.88	0.81	0.70	Lower limb	0.42	0.66

[a] Kappa value could not be calculated

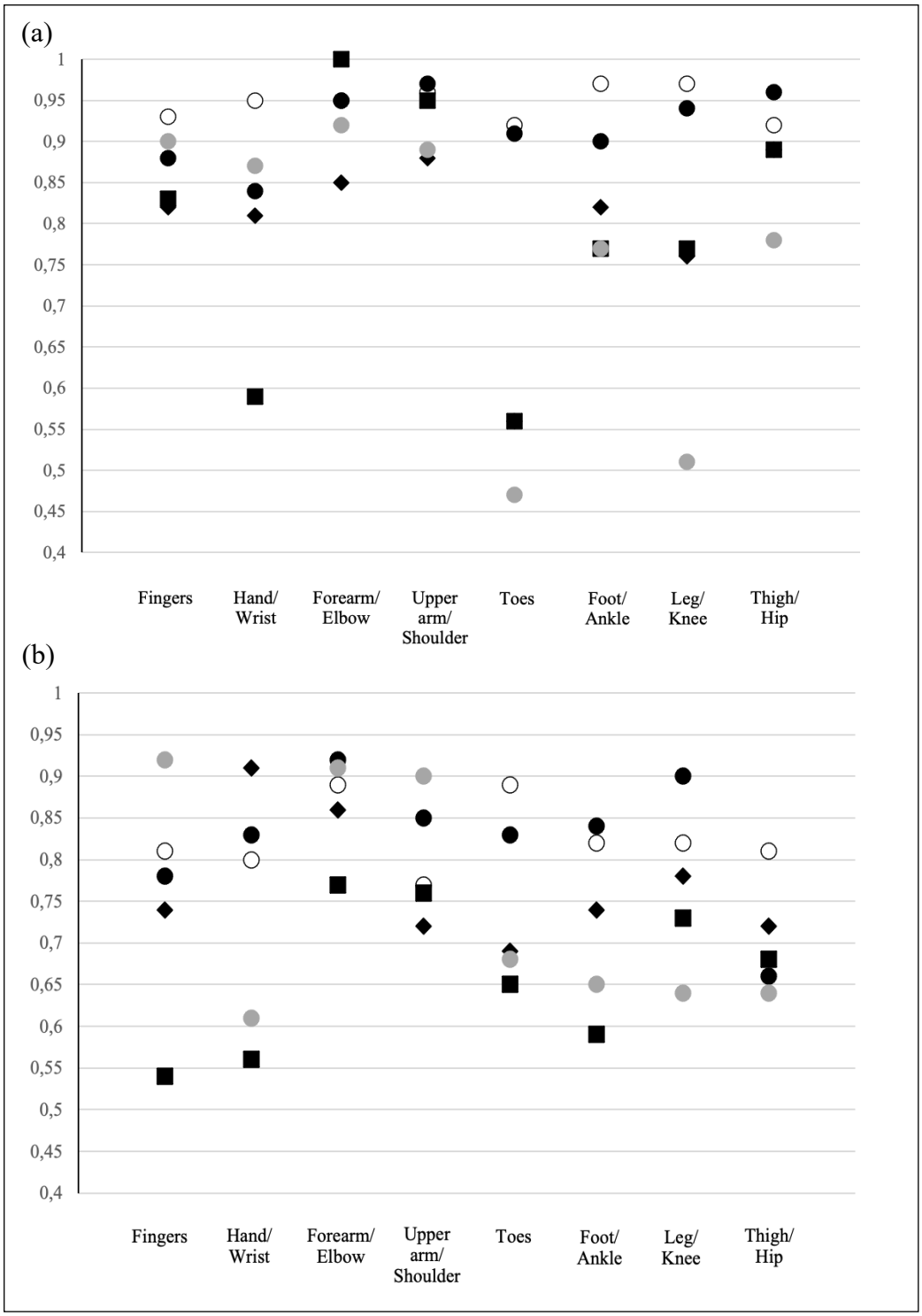

Figure 1. Weighted kappa values for (a) intra-rater and (b) inter-rater reliability ○ = light touch; ● = pressure; ■ = pinprick; ◆ = sharp/blunt discrimination; ● = proprioception

Reporting checklist for diagnostic test accuracy study.

Based on the STARD guidelines.

		Reporting Item	Page Number
Title or abstract			
None	#1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	Pag. 1, 4
Abstract			
None	#2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts https://www.equator-network.org/reporting-guidelines/stard-abstracts/)	Pag. 4
Introduction			
None	#3	Scientific and clinical background, including the intended use and clinical role of the index test	Pag. 5
None	#4	Study objectives and hypotheses	Pag. 5
Methods			
Study design	#5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	n/a
Participants	#6	Eligibility criteria	Pag. 7
Participants	#7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	Pag. 7

Participants	#8	Where and when potentially eligible participants were identified (setting, location and dates)	Pag. 7, 8
Participants	#9	Whether participants formed a consecutive, random or convenience series	Pag. 8
Test methods	#10	Index and reference tests in sufficient detail to allow replication	Pag. 8
Test methods	#11	Rationale for choosing the reference standard (if alternatives exist)	n/a
Test methods	#12	Definition of and rationale for test positivity cut-offs or result categories of the index and reference tests, distinguishing pre-specified from exploratory	Pag. 7, 8
Test methods	#13	Whether clinical information and reference standard results were available to the performers / readers of the index test; Whether clinical information and index test results were available to the assessors of the reference standard	n/a
Analysis	#14	Methods for estimating or comparing measures of diagnostic accuracy	Pag. 8
Analysis	#15	How indeterminate index test or reference standard results were handled	Pag. 8
Analysis	#16	How missing data on the index test and reference standard were handled	n/a
Analysis	#17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	n/a
Analysis	#18	Intended sample size and how it was determined	n/a
Results			
Participants	#19	Flow of participants, using a diagram	n/a
Participants	#20	Baseline demographic and clinical characteristics of participants	Pag. 9

Participants	#21	Distribution of severity of disease in those with the target condition, and distribution of alternative diagnoses in those without the target condition	Pag. 9
Participants	#22	Time interval and any clinical interventions between index test and reference standard	n/a
Test results	#23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	n/a
Test results	#24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Pag. 9
Test results	#25	Any adverse events from performing the index test or the reference standard	Pag. 9
Discussion			
None	#26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	Pag. 11
None	#27	Implications for practice, including the intended use and clinical role of the index test	Pag. 10, 11
Other information			
None	#28	Registration number and name of registry	n/a
None	#29	Where the full study protocol can be accessed	n/a
None	#30	Sources of funding and other support; role of funders	Pag. 12