Appendix J: Clinical evidence – completed methodology checklists for assessment studies

Abbreviations

ICD-10	International Classification of Diseases (10th revision)
	number of studies
PAS-ADD	Psychiatric Assessment Schedule for Adults with a Developmental Disability
QUADAS-2	Quality Assessment of Diagnostic Accuracy Studies version 2

A.2 Diagnostic test accuracy studies

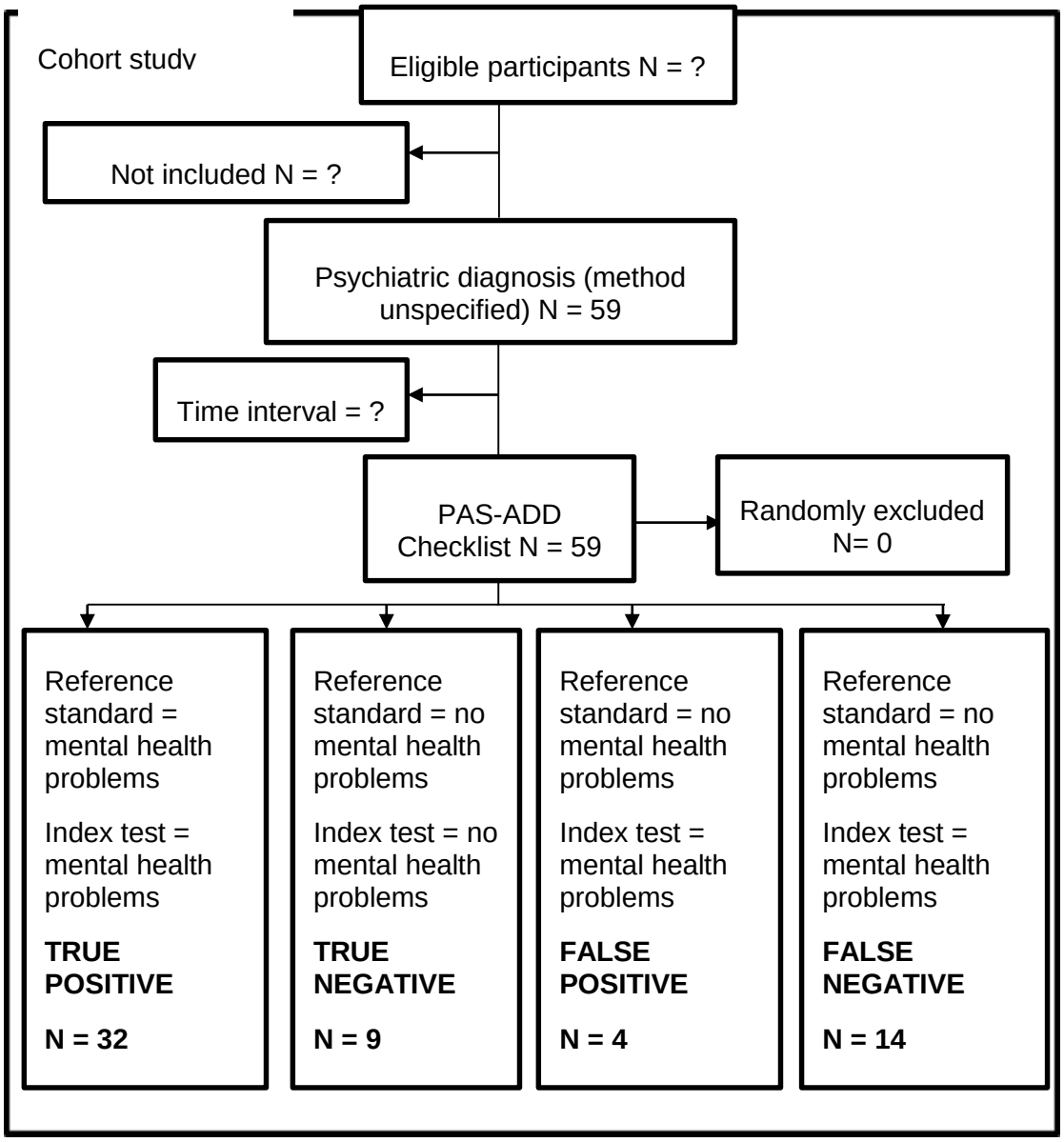
A.2.1 Moss 1998

Moss S, Prosser H, Costello H, Simpson N, Patel P, Rowe S, et al. Reliability and validity of the PAS-ADD Checklist for detecting psychiatric disorders in adults with intellectual disability. Journal of Intellectual Disability Research. 1998;42:173-83.

Phase 1: State the review question

Patients (setting, intended use of index test, presentation, prior testing): In people with learning disabilities, what is the utility of methods and tools used to assess the circumstances, risk factors and antecedents associated with the development of behaviour that challenges (including assessment of sensory deficits, sensory processing disorders, physical health status, communication needs, emotional needs, mental health needs, and environmental factors)?
Index test(s): Psychiatric Assessment Schedule for Adults with a Developmental Disability Checklist (PAS-ADD Checklist)
Reference standard and target condition: Reference standard was diagnosis by a psychiatrist (method unspecified) and target condition was mental health problems.

Phase 2: Draw a flow diagram for the primary study



Phase 3: Risk of bias and applicability judgements

Quality Assessment of Diagnostic Accuracy Studies version 2 (QUADAS-2) is structured so that four key domains are each rated in terms of the risk of bias and the concern regarding applicability to the review question (as stated in Phase 1). Each key domain has a set of signalling questions to help reach the judgements regarding bias and applicability.

Domain 1: Patient selection	
A. Risk of bias	
Describe methods of patient selection: Participants were individuals with intellectual disability on the psychiatrist's clinical files, some of whom were currently ill and some of whom were well. Subjects were selected to cover a broad range of conditions and severity of disorder.	
Was a consecutive or random sample of patients enrolled?	No
Was a case-control design avoided?	Yes
Did the study avoid inappropriate exclusions?	Unclear

Domain 1: Patient selection	
Could the selection of patients have introduced bias? Risk: High	
B. Concerns regarding applicability	
Describe included patients (prior testing, presentation, intended use of index test and setting): Participants were 59 individuals with intellectual disability. Subjects were selected to cover a broad range of conditions and severity of disorder. According to the reference standard, 15% had no diagnosis; 7% were in remission; 3% were diagnosed with dementia; 8% with organic mental illness; 25% with schizophrenia or psychosis; 10% with bipolar disorder; 24% with depression; 3% with acute stress reaction; 3% with an eating disorder; 3% with sexual dysfunction and 3% with hyperactivity.	
Is there concern that the included patients do not match the review question? Concern: Low	

Domain 2: Index test(s)	
A. Risk of bias	
Describe the index test and how it was conducted and interpreted: The PAS-ADD Checklists were completed by key informants, who were staff members or relatives in the majority of cases. The informants completing the PAS-ADD Checklist were kept blind to the scoring algorithm. There were 6 sample members who had a diagnosis that was not in the spectrum covered by the PAS-ADD Checklist; therefore, it was considered less likely that these would be detected by the instrument. (For the purpose of this review question all participants, including those with a diagnosis not covered by the PAS-ADD Checklist have been included in analysis to prevent artificially inflating sensitivity and specificity estimates).	
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear
If a threshold was used, was it pre-specified?	Yes
Could the conduct or interpretation of the index test have introduced bias? Risk: Unclear	
B. Concerns regarding applicability	
Is there concern that the index test, its conduct, or interpretation differ from the review question? Concern: Low	

Domain 3: Reference standard	
A. Risk of bias	
Describe the reference standard and how it was conducted and interpreted: The reference standard was an estimate of severity of illness made by one of the authors - a psychiatrist specializing in intellectual disability. Each subject was given a current diagnosis and an estimate of severity on a three-point scale: (0) well or in remission; (1) mild; and (2) severe. It is not reported whether the assessor was blind to results of the index test.	
Is the reference standard likely to correctly classify the target condition?	Unclear
Were the reference standard results interpreted without knowledge of the results of the index test?	Unclear
Could the reference standard, its conduct, or its interpretation have introduced bias? Risk: Unclear	
B. Concerns regarding applicability	
Is there concern that the target condition as defined by the reference standard does not match the review question? Concern: Unclear	

Domain 4: Flow and timing	
A. Risk of bias	
Describe any patients who did not receive the index test(s) and/or reference standard or who were excluded from the 2 × 2 table (refer to flow diagram): According to the paper, there were no participants excluded from the study. Describe the time interval and any interventions between index test(s) and reference standard: The time interval and any interventions between index test and reference standard were not reported.	
Was there an appropriate interval between index test(s) and reference standard?	Unclear
Did all patients receive a reference standard?	Yes
Did patients receive the same reference standard?	Unclear
Were all patients included in the analysis?	Yes
Could the patient flow have introduced bias? Risk: Unclear	

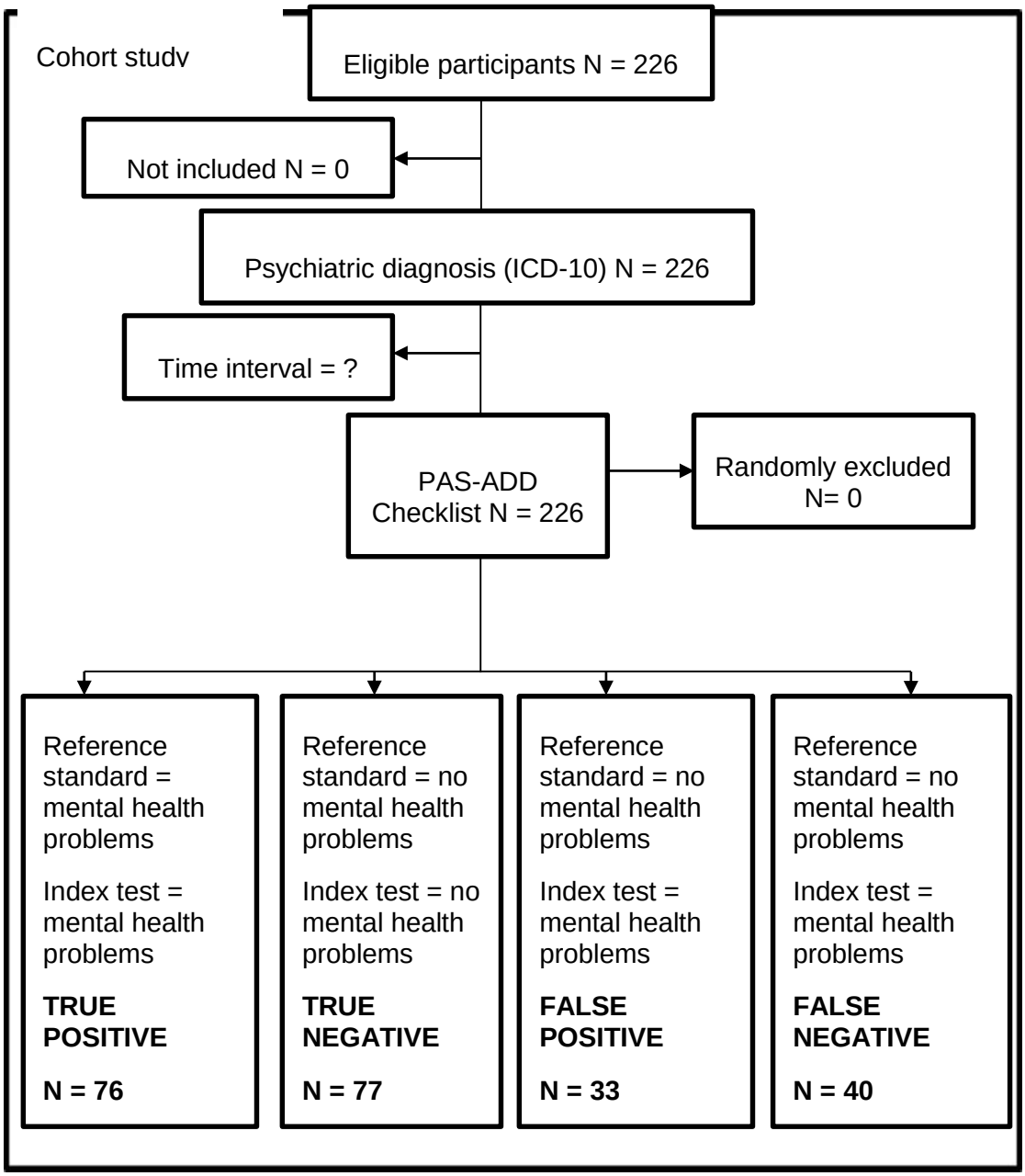
A.2.2 Sturmey 2005

Sturmey P, Newton JT, Cowley A, Bouras N, Holt G. The PAS-ADD Checklist: Independent replication of its psychometric properties in a community sample. British Journal of Psychiatry. 2005;186:319-23.

Phase 1: State the review question

Patients (setting, intended use of index test, presentation, prior testing): In people with learning disabilities, what is the utility of methods and tools used to assess the circumstances, risk factors and antecedents associated with the development of behaviour that challenges (including assessment of sensory deficits, sensory processing disorders, physical health status, communication needs, emotional needs, mental health needs, and environmental factors)?
Index test(s): PAS-ADD Checklist
Reference standard and target condition: Reference standard was the International Classification of Diseases (10th revision) (ICD-10) and target condition was psychopathology.

Phase 2: Draw a flow diagram for the primary study



Phase 3: Risk of bias and applicability judgements

QUADAS-2 is structured so that four key domains are each rated in terms of the risk of bias and the concern regarding applicability to the review question (as stated in Phase 1). Each key domain has a set of signalling questions to help reach the judgements regarding bias and applicability.

Domain 1: Patient selection	
A. Risk of bias	
Describe methods of patient selection: The sample comprised all 226 individuals who were referred over a 3-year period to a specialist mental health service for people with intellectual disabilities	
Was a consecutive or random sample of patients enrolled?	Yes
Was a case-control design avoided?	Yes
Did the study avoid inappropriate exclusions?	Yes

Domain 1: Patient selection	
Could the selection of patients have introduced bias? Risk: Low	
B. Concerns regarding applicability	
Describe included patients (prior testing, presentation, intended use of index test and setting): Participants were individuals who were referred to a specialist mental health service for people with intellectual disabilities. 35% had no psychiatric diagnosis; 19% schizophrenia spectrum diagnosis; 12% depressive disorder; 8% anxiety; 8% adjustment reaction; 4% dementia; 8% personality disorder; 6% other (delirium, eating disorder, hyperkinetic disorder).	
Is there concern that the included patients do not match the review question? Concern: Low	

Domain 2: Index test(s)	
A. Risk of bias	
Describe the index test and how it was conducted and interpreted: A key informant such as a relative or staff member was asked to complete the PAS–ADD Checklist for each individual. 14% of participants had ICD-10 disorders not covered by the PAS-ADD Checklist. The number of participants with no diagnosis and those with an ICD-10 diagnosis not covered by the checklist have been combined in the data reported in Table 5 of Sturmey 2005 (Table 5) and thus it is not possible to separate out the proportion of these which would fall into false negatives and true negatives. It is possible that this could inflate estimates of diagnostic precision).	
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear
If a threshold was used, was it pre-specified?	Unclear
Could the conduct or interpretation of the index test have introduced bias? Risk: Unclear	
B. Concerns regarding applicability	
Is there concern that the index test, its conduct, or interpretation differ from the review question? Concern: High	

Domain 3: Reference standard	
A. Risk of bias	
Describe the reference standard and how it was conducted and interpreted: The target condition was psychopathology and the reference standard was ICD-10. The assessing psychiatrist was masked to the PAS-ADD Checklist score at assessment.	
Is the reference standard likely to correctly classify the target condition?	Yes
Were the reference standard results interpreted without knowledge of the results of the index test?	Yes
Could the reference standard, its conduct, or its interpretation have introduced bias? Risk: Low	
B. Concerns regarding applicability	
Is there concern that the target condition as defined by the reference standard does not match the review question? Concern: Low	

Domain 4: Flow and timing	
A. Risk of bias	
Describe any patients who did not receive the index test(s) and/or reference standard or who were excluded from the 2 × 2 table (refer to flow diagram): According to the paper, there were no participants excluded from the study. Describe the time interval and any interventions between index test(s) and reference standard: The time interval and any interventions between index test and reference standard were not reported.	
Was there an appropriate interval between index test(s) and reference standard?	Unclear
Did all patients receive a reference standard?	Yes
Did patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Could the patient flow have introduced bias? Risk: Unclear	

Note:

For the accompanying notes on how to use the QUADAS-2 tool, please see the QUADAS website and:

Whiting PF, Rutjes AWS, Westwood ME, Mallett S, Deeks JJ, QUADAS-2 group, et al. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Annals of Internal Medicine. 2011;155:529–36.