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Creavin, S. T., Wisniewski, S., Noel-Storr, A. H., Trevelyan, C. M., Hampton, T., Rayment, D., ... Cullum, S. J. (2016). Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations. Cochrane Database of Systematic Reviews, 2016(1), [CD011145.pub2]. DOI: 10.1002/14651858.CD011145.pub2

Publisher's PDF, also known as Version of record

Link to published version (if available):
10.1002/14651858.CD011145.pub2

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Cochrane Database of Systematic Reviews 2016, Issue 1. Art. No.: CD011145.
DOI: 10.1002/14651858.CD011145.pub2.

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[Diagnostic Test Accuracy Review]

Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

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Editorial group: Cochrane Dementia and Cognitive Improvement Group.
Publication status and date: Edited (no change to conclusions), published in Issue 4, 2016.
Review content assessed as up-to-date: 31 May 2014.

Citation: Creavin ST, Wisniewski S, Noel-Storr AH, Trevelyan CM, Hampton T, Rayment D, Thom VM, Nash KJE, Elhamoui H, Milligan R, Patel AS, Tsivos DV, Wing T, Phillips E, Kellman SM, Shackleton HL, Singleton GF, Neale BE, Watton ME, Cullum S. Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations. *Cochrane Database of Systematic Reviews* 2016, Issue 1. Art. No.: CD011145. DOI: 10.1002/14651858.CD011145.pub2.

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ABSTRACT

Background

The Mini Mental State Examination (MMSE) is a cognitive test that is commonly used as part of the evaluation for possible dementia.

Objectives

To determine the diagnostic accuracy of the Mini-Mental State Examination (MMSE) at various cut points for dementia in people aged 65 years and over in community and primary care settings who had not undergone prior testing for dementia.

Search methods

We searched the specialised register of the Cochrane Dementia and Cognitive Improvement Group, MEDLINE (OvidSP), EMBASE (OvidSP), PsycINFO (OvidSP), LILACS (BIREME), ALOIS, BIOSIS previews (Thomson Reuters Web of Science), and Web of Science Core Collection, including the Science Citation Index and the Conference Proceedings Citation Index (Thomson Reuters

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Web of Science). We also searched specialised sources of diagnostic test accuracy studies and reviews: MEDION (Universities of Maastricht and Leuven, www.mediondatabase.nl), DARE (Database of Abstracts of Reviews of Effects, via the Cochrane Library), HTA Database (Health Technology Assessment Database, via the Cochrane Library), and ARIF (University of Birmingham, UK, www.arif.bham.ac.uk). We attempted to locate possibly relevant but unpublished data by contacting researchers in this field. We first performed the searches in November 2012 and then fully updated them in May 2014. We did not apply any language or date restrictions to the electronic searches, and we did not use any methodological filters as a method to restrict the search overall.

Selection criteria

We included studies that compared the 11-item (maximum score 30) MMSE test (at any cut point) in people who had not undergone prior testing versus a commonly accepted clinical reference standard for all-cause dementia and subtypes (Alzheimer disease dementia, Lewy body dementia, vascular dementia, frontotemporal dementia). Clinical diagnosis included all-cause (unspecified) dementia, as defined by any version of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM); International Classification of Diseases (ICD) and the Clinical Dementia Rating.

Data collection and analysis

At least three authors screened all citations.Two authors handled data extraction and quality assessment. We performed meta-analysis using the hierarchical summary receiver-operator curves (HSROC) method and the bivariate method.

Main results

We retrieved 24,310 citations after removal of duplicates. We reviewed the full text of 317 full-text articles and finally included 70 records, referring to 48 studies, in our synthesis. We were able to perform meta-analysis on 28 studies in the community setting (44 articles) and on 6 studies in primary care (8 articles), but we could not extract usable 2 x 2 data for the remaining 14 community studies, which we did not include in the meta-analysis. All of the studies in the community were in asymptomatic people, whereas two of the six studies in primary care were conducted in people who had symptoms of possible dementia. We judged two studies to be at high risk of bias in the patient selection domain, three studies to be at high risk of bias in the index test domain and nine studies to be at high risk of bias regarding flow and timing. We assessed most studies as being applicable to the review question though we had concerns about selection of participants in six studies and target condition in one study.

The accuracy of the MMSE for diagnosing dementia was reported at 18 cut points in the community (MMSE score 10, 14-30 inclusive) and 10 cut points in primary care (MMSE score 17-26 inclusive). The total number of participants in studies included in the meta-analyses ranged from 37 to 2727, median 314 (interquartile range (IQR) 160 to 647). In the community, the pooled accuracy at a cut point of 24 (15 studies) was sensitivity 0.85 (95% confidence interval (CI) 0.74 to 0.92), specificity 0.90 (95% CI 0.82 to 0.95); at a cut point of 25 (10 studies), sensitivity 0.87 (95% CI 0.78 to 0.93), specificity 0.82 (95% CI 0.65 to 0.92); and in seven studies that adjusted accuracy estimates for level of education, sensitivity 0.97 (95% CI 0.83 to 1.00), specificity 0.70 (95% CI 0.50 to 0.85). There was insufficient data to evaluate the accuracy of the MMSE for diagnosing dementia subtypes.We could not estimate summary diagnostic accuracy in primary care due to insufficient data.

Authors' conclusions

The MMSE contributes to a diagnosis of dementia in low prevalence settings, but should not be used in isolation to confirm or exclude disease. We recommend that future work evaluates the diagnostic accuracy of tests in the context of the diagnostic pathway experienced by the patient and that investigators report how undergoing the MMSE changes patient-relevant outcomes.

PLAIN LANGUAGE SUMMARY

Mini-Mental State Examination (MMSE) for the detection of dementia in people aged over 65

The term 'dementia' covers a group of brain problems that cause gradual deterioration of brain function, thinking skills, and ability to perform everyday tasks (e.g. washing and dressing). People with dementia may also develop problems with their mental health (mood and emotions) and behaviour that are difficult for other people to manage or deal with. The process that causes dementia in the brain is often degenerative (due to brain damage over time). Subtypes of dementia include Alzheimer's disease dementia, vascular dementia, dementia with Lewy bodies and frontotemporal dementia.

We aimed to assess the accuracy of the Mini-Mental State Examination (MMSE), which is commonly used as part of the process when considering a diagnosis of dementia, according to the definition in the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM*).

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The MMSE is a paper-based test with a maximum score of 30, with lower scores indicating more severe cognitive problems. The cut point established for the MMSE defines 'normal' cognitive function and is usually set at 24, although theoretically it could fall anywhere from 1 to 30. We searched a wide range of resources and found 24,310 unique citations (hits). We reviewed the full text of 317 academic papers and finally included 70 articles, referring to 48 studies in our review. We included community studies (by which we mean people living in the community who have) and primary care studies (by which we mean studies that had an office-based first contact care with a non specialist clinician - which would often be a GP).

Two of the studies had serious design weaknesses with regard to their methods for selecting participants, three with regard to the application of the test (MMSE), and nine with regard to the presentation of flow and timing. We were able to do a combined statistical analysis (meta-analysis) on 28 studies in the community setting (44 articles) and 6 studies in primary care (8 articles), but we could not extract usable data for the remaining 14 community studies. Two of the six studies in primary care were conducted in people who had symptoms of possible dementia. We were able to calculate the summary diagnostic accuracy of the MMSE at three cut points in community-based studies, but we didn't have enough data to do this in the primary care studies. A perfect test would have sensitivity (ability to identify anyone with dementia) of 1.0 (100%) and specificity (ability to identify people without dementia) of 1.0 (100%). For the MMSE, the summary accuracy at a cut point of 25 (10 studies) was sensitivity 0.87 and specificity 0.82. In seven studies that adjusted accuracy estimates for level of education, we found that the test had a sensitivity of 0.97 and specificity of 0.70. The summary accuracy at a cut point of 24 (15 studies) was sensitivity 0.85 and specificity 0.90. Based on these results, we would expect 85% of people with dementia to be correctly identified with the MMSE, while 15% would be wrongly classified as not having dementia; 90% of those tested would be correctly identified as not having dementia whilst 10% would be false positives and might be referred for further testing.

Our results support the use of the MMSE as part of the process for deciding whether or not someone has dementia, but the results of the test should be interpreted in broader context of the individual patient, such as their personality, behaviour and how they are managing at home and in daily life.

BACKGROUND

The protocol for this review was based on 'Neuropsychological tests for the diagnosis of Alzheimer's disease dementia and other dementias: a generic protocol for cross-sectional and delayed-verification studies' (Davis 2013a). This review forms part of a suite of reviews that address the accuracy of different neuropsychological tests for the cross-sectional and delayed-verification diagnosis of dementia in a range of populations, for example the the Montreal Cognitive Assessment for the diagnosis of Alzheimer's disease and other dementia disorders (Davis 2013b), the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) for the diagnosis of Alzheimer's disease dementia and other dementias within a general practice (primary care) setting (Quinn 2013); Mini-Cog for the diagnosis of Alzheimer's disease dementia and other dementias within a community setting (Fage 2013) and Mini-Mental State Examination (MMSE) for the detection of Alzheimer's disease and other dementias in people with mild cognitive impairment (Arevalo-Rodriguez 2013).

This review addresses the use of the Mini-Mental State Examination (MMSE) for the cross-sectional (current) diagnosis of Alzheimer's dementia and other dementias when used in the community and primary care, which are populations with a relatively low prevalence of dementia (approximately 7%; Matthews 2013) compared to memory clinics (around 60%; Banerjee 2007) and secondary or inpatient care. We included studies that examine the accuracy of the MMSE in previously unevaluated people with or without symptoms (akin to screening) because we aimed to address the accuracy of the MMSE when applied to the clinically relevant question of patients and clinicians, 'Does this person have dementia now?'. A separate review evaluates the accuracy of the MMSE for delayed verification of dementia diagnosis at some future point (addressing the question, 'Is the current level of cognition sufficiently poor that this person has a pre-dementia syndrome?').

Target condition being diagnosed

Dementia is a progressive syndrome of global cognitive impairment that affects 6.5% of the UK population aged over 65 years (Matthews 2013). There is a significant global disease burden (36 million patients worldwide) that is predicted to increase to over 115 million by 2050, particularly in developing regions (Ferri 2005; Wimo 2010). Dementia encompasses a group of neurodegenerative disorders that are characterised by a progressive loss of cognitive function and ability to perform activities of daily living

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that can be accompanied by neuropsychiatric symptoms and challenging behaviours of varying type and severity. Prior ability is also important: someone could have a decline in their cognition over time and meet criteria for a diagnosis of dementia while still scoring above average on a cognitive test. The underlying pathology is usually degenerative, and subtypes of dementia include Alzheimer's disease dementia, vascular dementia, dementia with Lewy bodies (pathological clusters of alpha-synuclein protein; McKeith 2005), and frontotemporal dementia. There is considerable overlap in the clinical and pathological presentations; for example, Alzheimer's disease pathology may be present in people who have a clinical phenotype of vascular or Lewy body dementia, and vascular changes and Lewy bodies are common in the postmortem examination of brains of people with an Alzheimer's disease phenotype (CFAS 2001; Matthews 2009; Savva 2009). Some commentators have therefore advised against the use of neuropathological criteria as the gold standard for the diagnosis of dementia, including subtypes (Scheltens 2011).

The target condition in this review will be dementia or its subtypes (as defined by the reference standards described below), identified simultaneously with the administration of the index test.

Index test(s)

The Folstein Mini-Mental State Examination (MMSE) is an 11-item assessment of cognitive function that assesses attention and orientation, memory, registration, recall, calculation, language and ability to draw a complex polygon (Folstein 1975). The MMSE is subject to copyright restrictions (De Silva 2010), and it takes around seven minutes to administer to a person with dementia and five minutes to a person with normal cognition (Borson 2000). Scores can range from 1 to 30; the conventional cut-off is 24, with lower scores indicating increasing cognitive impairment (Mitchell 2009), although other cut-off points have been suggested (Crum 1993; Kukull 1994). There is a wide spectrum in the severity of disease that people with dementia have, and this will affect the diagnostic properties of a diagnostic test such as the MMSE.

Clinical pathway

Dementia develops over several years, from a presumed initial asymptomatic period where pathological changes accumulate in the absence of clinical manifestations, through subtle impairments of recent memory or changes in personality or behaviour, until the disease has become more apparent, with multiple cognitive domains involved and a noticeable decline from previous abilities in planning and performing complex tasks.

Standard diagnostic practice

Standard diagnostic assessment relates to evaluating people for whom there is concern about possible dementia, particularly to exclude alternative diagnostic hypotheses, and it includes history, clinical examination (including neurological, mental state and cognitive examination) and an interview with a relative or other informant. Before diagnosing dementia, other physical and mental disorders that might be contributing to cognitive impairment, for example hypothyroidism or depression, should be identified and if possible treated. Most recent guidelines recommend a neuroradiological examination to scan the brain (Computed Tomography (CT) or Magnetic Resonance Imaging (MRI)) to exclude structural causes for the clinical phenotype, for example a subdural haematoma (McKhann 2011; NICE 2006), but sometimes clinicians make the diagnosis on the history and presentation alone. Dementia diagnosis is defined by a deficit in more than two cognitive domains of sufficient degree to impair functional activities. These symptoms are usually progressive over a period of at least several months and should not be attributable to any other brain disorder. The International Classification of Diseases, 10th edition (ICD-10) and the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) general diagnostic criteria for dementia are detailed in Appendix 1 (APA 1994; WHO 1992).

Screening

Screening is the identification of unrecognised or asymptomatic disease by the administration of tests that can be applied quickly and are not intended to be diagnostic (Porta 2008). Recent UK health policy has encouraged opportunistic testing of older people attending primary care who have presented for reasons other than a memory complaint (Brunet 2012; Le Couteur 2013; Rasmussen 2013). GPs in the UK are encouraged to actively find people with dementia through routine annual questions in a Direct Enhanced Service (DOH recommendations; NICE 2013). In some cases, after further evaluation, the GP may then make a diagnosis of dementia, with or without a subtype (Ahmad 2010). Dementia screening is not recommended by the United States Preventive Services Task Force (US Preventive Services 2003), but the Patient Protection and Affordable Care Act requires an annual assessment of cognition for people who are enrolled in Medicare (Cordell 2013). The UK government has also encouraged case finding for dementia on acute admission to secondary care services (Dementia CQUIN).

Because people with dementia may not experience subjective memory problems, and a diagnosis of dementia often requires diagnostic evaluation by an experienced clinician, triage tests such as the MMSE are used in clinical practice to help rapidly identify people with a high likelihood of having normal cognition who do not require onward referral and investigation. Some investigations have blurred the distinction between the use of tests as a screening instrument in individuals without manifest disease and their use as clinical triage tools (Kamenski 2009).

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Presentation to health services

In the UK people with memory problems usually present initially to their primary care practitioner, who may administer the MMSE to 'rule in' or confirm the *possibility* of dementia and potentially refer the patient to a specialist hospital memory clinic. Some people with dementia present much later in the disorder or follow a different pathway to diagnosis, for example, during an admission to general hospital for a physical illness. Diagnostic assessment pathways may vary in other countries, and a variety of clinicians including neurologists, psychiatrists and geriatricians, may make the diagnoses.

Role of the index test

Many countries in Europe and worldwide have been developing dementia strategies that emphasise the importance of accurate diagnosis to access appropriate health and social care services. Despite copyright restrictions, current experience is that the MMSE is still used extensively in clinical practice (Su 2014), including in the primary care setting, where clinicians may use it as either a screening test for dementia or as part of a more detailed evaluation of a person with suspected dementia. In some people, for example those who are particularly frail or unable to travel to a specialist clinic, the MMSE may be the only cognitive test used as part of the evaluation for possible dementia. A systematic evaluation of the diagnostic test accuracy of the instrument is needed to determine what confidence patients and clinicians can have in the clinical diagnosis of dementia based on the MMSE. A confirmed diagnosis of dementia is believed to offer opportunities for interventions, both social and medical, which may reduce the associated behavioural and psychiatric symptoms of dementia (Birks 2006; Clare 2003; McShane 2006), helping people with dementia, their families and potential caregivers to plan and avoid admissions to hospital or institutional care (Bourne 2007).

Prior tests

We anticipated the likelihood that no prior tests would have been performed before evaluating patients. In some settings, a two-stage screening and assessment process takes place. Screening of people with suspected dementia usually requires a brief test of cognitive function, informant questionnaires or both, with a low score indicating a need for more in-depth assessment (Boustani 2003). We anticipated that some studies carried out in the community and in primary care may have administered a very brief, high sensitivity instrument before applying the MMSE and investigating all of those who screened positive and a subsample of those who screened negative. In this eventuality, we planned to include the study and consider the prior test as a potential source of heterogeneity. However, no study used a test prior to the MMSE. Other tests are available to screen for dementia in primary care (Tsoi 2015), but we limited our review to the MMSE.

Rationale

Policy for dementia diagnosis is developing rapidly and has changed since the publication of the generic protocol for neuropsychological tests (Davis 2013a). There is a great need for a systematic appraisal of the diagnostic accuracy of neuropsychological tests, including the MMSE, in unselected (clinically unevaluated) populations.

OBJECTIVES

To determine the diagnostic accuracy of the Mini-Mental State Examination (MMSE) at various cut points for dementia in people aged 65 years and over in community and primary care settings who had not undergone prior testing for dementia.

Secondary objectives

To investigate the heterogeneity of test accuracy in the included studies. We anticipated that there would be many potential sources of heterogeneity in this review, which Davis 2013a covered fully. In this review we expected that the most important sources of heterogeneity would be the characteristics of the study populations, the way investigators used the MMSE and the reference standard employed.

METHODS

Criteria for considering studies for this review

Types of studies

The inclusion criteria for studies in this review were based on the generic protocol for neuropsychological tests in dementia (Davis 2013a). We reviewed the diagnostic accuracy of the MMSE when used in people aged over 65 years in non-specialist settings, including community settings (population-based screening) and primary care settings (where people may be screened opportunistically or present to the primary care practitioner with memory problems). We included studies that examined the diagnostic accuracy of the MMSE in people considered to have a memory problem (by patient, informant or clinician), as well as screening studies that examined the diagnostic accuracy in people regardless of a memory complaint (asymptomatic people). We analysed studies separately based on whether they were screening studies or not, as described

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in Investigations of heterogeneity. We included a diagnosis of dementia at any stage of disease (as long as the dementia was not previously identified by a specialist), as we considered that this pragmatic approach was most likely to be useful in informing current health policy and clinical practice. We did not examine the accuracy of MMSE for the diagnosis of pre-clinical dementia (Sperling 2011), as this will be the subject of a separate review.

We included cross-sectional studies that administered the index test and the reference standard(s) within a short time span (less than six months). We excluded case-control studies because of the risk of bias (Whiting 2013). We did not include delayed verification studies, as these will be examined in a separate review, as described in the Background. We included studies where we anticipated 2 x 2 data would be available even if it was not reported in the original paper, and we contacted the authors to obtain it where necessary. Figure 1 outlines the process that we used for including articles in the review; further details are given in Selection of studies.

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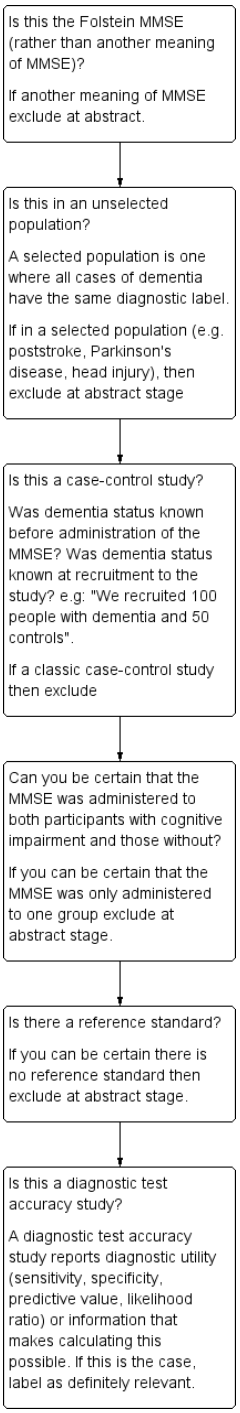
Figure 1. Inclusion of studies



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Participants

We included all participants who met the criteria for inclusion in community-based or primary care described above. We defined primary care as non-specialist, office-based care with a first-contact healthcare provider. We excluded studies where the MMSE was administered in a secondary care population, for example an emergency department, neurology ward or memory clinic.

We excluded studies of participants with previous or current substance abuse, central nervous system trauma (e.g. subdural haematoma), tumour or infection. Similarly, we excluded studies that recruited participants solely on the basis of disease state (for example; Parkinson's disease, multiple sclerosis, brain injury, motor neurone disease) or residence (for example; residential home, nursing home, prison), as they are not applicable to the general population. We considered that studies that recruited participants conditional on these criteria would have a different prevalence of dementia than the general population. We included studies that recruited participants from retirement communities (defined as non-nursing elderly person independent facilitated living communities but not residential homes where multiple elderly people from different families lived in a single building with resident carers), as we considered that residents in these settings are likely to be similar to the population in terms of cognition and co-morbidities.

Our intention was that the findings of this review would have relevance to clinicians in community health and primary care, and be applicable to people with 'usual dementia' (Brayne 2012). We therefore excluded studies that investigated specific clinical groups. For example, participants with a family history of Alzheimer's dementia may be more readily diagnosed with dementia, perhaps leading to verification bias. On this basis, we excluded studies that exclusively investigated people with a known genetic predisposition from this review and studies specifically investigating early-onset dementia.

Examples of applicable studies for this review include the following.

- Participants selected regardless of suspicion of cognitive disorder. This would be an unselected cross-sectional survey that administered the MMSE to all participants and then evaluated all participants (or a random sample), regardless of MMSE result, with a full assessment for the presence or absence of the target disorder. These studies are analogous to screening and could be conducted in:
    - the community;
    - people attending primary care, as defined in Participants section, though we considered these studies would be uncommon as they would involve screening people for cognitive disorder in a doctor's office waiting room, and the ethics of this are not established.
- Participants selected as being suspected of having cognitive disorder. These studies could be conducted in:
    - the community, though we anticipated these studies would be uncommon, as many people who are suspected of having cognitive disorder will seek evaluation in a healthcare setting;
    - primary care.

Thus, we anticipated that we might find studies using the MMSE in two different ways (evaluating people with and without suspicion of cognitive disorder) in two different clinical settings (community, before seeking diagnostic evaluation; and primary care, at the point of seeking diagnostic evaluation). We expected the diagnostic accuracy of the MMSE to differ between studies based in community and in primary care populations (and particularly in primary care participants selected on the basis of memory symptoms), and we planned to conduct separate analyses in these four potential study populations if appropriate.

Index tests

The index test is the 11-item (maximum score 30) MMSE test (Folstein 1975). We recognised that other versions of the test exist (Grace 1995; Harrell 2000; Haubois 2012; Kabir 2000; Molloy 1991; Tschanz 2002), but we considered that these were best investigated in separate studies because of the substantial heterogeneity in the diagnostic test performance of these instruments. We also judged that including these index test variants would create an unfeasible workload for this review. However, we did not exclude studies on the basis of language, and we included studies that reported, for example, the diagnostic test accuracy of the Korean version of the 11-item MMSE. Because education is associated with dementia (Fratiglioni 1991), some studies adjust the MMSE score for educational attainment (e.g. Liu 1996a).

Target conditions

The target condition was all-cause dementia and any dementia subtype. We expected to find studies that focused on all-cause dementia, Alzheimer disease dementia, vascular dementia, Lewy body dementia and frontotemporal dementia. We planned to appraise findings separately if we could extract included studies examining dementias of differing aetiologies or differing stages.

Reference standards

In this review, the target condition was dementia or its subtypes as defined by the clinical reference standards described in Davis

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2013a and outlined below. We excluded studies that used neuropathological criteria as the only reference standard, as this review seeks to determine a cross-sectional diagnosis of dementia. Clinical diagnosis included all-cause (unspecified) dementia, as defined by any version of the DSM, which when conducting the review was most recently the fourth edition (APA 1994); any version of ICD, which when conducting the review was most recently ICD, 10th edition (WHO 1992) (see Appendix 1); or the Clinical Dementia Rating (Morris 1993). In studies in which a reference standard refers to different criteria for dementia (for example McKhann 1984: unlikely, possible, probable, definite), we considered people as having the disease if they were classified as having either probable or definite dementia.

Alzheimer's dementia

The National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) have proposed the best ante-mortem, clinical consensus 'reference standard' for Alzheimer's disease, defining three ante-mortem groups: probable, possible, and unlikely Alzheimer's dementia (McKhann 1984). Newer criteria for Alzheimer's disease introduced in 2011 include the use of biomarkers (such as brain imaging and cerebrospinal fluid analysis) to contribute to diagnostic categories (McKhann 2011). We planned to present any studies that used these (biomarker) criteria in a separate category and to test the findings in a sensitivity analysis.

Lewy body dementia

The reference standard for Lewy body dementia is the McKeith criteria or their revision (McKeith 1996; McKeith 2005).

Frontotemporal dementia

The reference standard for frontotemporal dementia is the Lund criteria (Lund 1994).

Vascular dementia

The reference standard for vascular dementia is the National Institute of Neurological and Communicative Disorders and Stroke and the Association Internationale pour la Recherché et l'Enseignement en Neurosciences (NINCDS-AIREN) criteria (Román 1993).

We recognised that different iterations of reference standards over time may not be directly comparable (e.g. DSM-III-R versus DSM-IV, ICD-9 versus ICD-10) and that the validity of diagnoses may vary with the degree or manner in which the criteria have been applied (e.g. individual clinician versus algorithm versus consensus determination). We collected data on the method and application of the reference standard, and we planned to examine this as a source of heterogeneity if we considered it to be a source of bias. Although it is unlikely that a specific reference standard might favour particular index tests, there is the more general issue of incorporation bias, in which the reference standard is applied with knowledge of the index test because neuropsychological deficits are integral to the definition of dementia. This is less problematic in cross-sectional studies because the index test and the reference standard may be administered completely independently.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Dementia and Cognitive Improvement Group's specialised register (via the Cochrane Register of Studies); MEDLINE (OvidSP) (January 1946 to May 2014); EMBASE (OvidSP) (January 1972 to May 2014); BIOSIS previews (Thomson Reuters Web of Science) (January 1922 to May 2014); Web of Science Core Collection, including the Science Citation Index and the Conference Proceedings Citation Index (Thomson Reuters Web of Science) (January 1945 to May 2014); PsycINFO (OvidSP) (January 1806 to May 2014) and LILACS (BIREME). See Appendix 2 for the search strategies. Where appropriate, we used controlled vocabulary such as MeSH terms (in MEDLINE) and EMTREE (in EMBASE) and other controlled vocabulary in other databases, as appropriate. We did not use search filters designed to retrieve diagnostic test accuracy studies (collections of terms aimed at reducing the number needed to screen by filtering out irrelevant records and retaining only those that are relevant) as a method to restrict the search overall, because available filters have not yet proved sensitive enough for systematic review searches (Beynon 2013; Whiting 2011). We did not apply any language restriction to the electronic searches; we used translation services as necessary during the screening stages.

A single researcher with extensive experience in systematic reviews performed the searches. We first performed the searches on 21 November 2012 and then again on 20 May 2014.

Searching other resources

We checked the reference lists of all relevant papers for additional studies. We also searched:

- Meta-analyses van Diagnostisch Onderzoek (MEDION database) (www.mediondatabase.nl);
- Database of Abstracts of Reviews of Effects (DARE) (www.cochranelibrary.com);
- Health Technology Assessments Database (HTA Database) in *The Cochrane Library* (www.cochranelibrary.com);
- Aggressive Research Intelligence Facility (ARIF database) (www.arif.bham.ac.uk).

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We attempted to contact authors where necessary to obtain details of unpublished studies.

Data collection and analysis

Selection of studies

Figure 1 shows a flowchart that we used when considering whether to include studies in the review.

The inclusion criteria were:

- population is either community or primary care (see 'Types of studies');
- reference standards as described above;
- MMSE was used as an index test (alone or with other tests) and was administered to all study participants;
- study design is cohort or nested case-control.

Exclusion criteria were:

- classic case-control study design (subject to spectrum bias);
- index test administered to only cases or controls, rather than to both groups (cannot calculate diagnostic accuracy).

We selected studies based on the title and abstract screening undertaken by a team of trained assessors. Two assessors independently reviewed all citations retrieved by the searches and classified them as relevant or not. Pairs of authors then assessed the full-text papers of studies classified as possibly relevant, and we resolved any disagreements by discussion with a third, senior author. We show the process of study selection in a PRISMA flow diagram in Figure 2.

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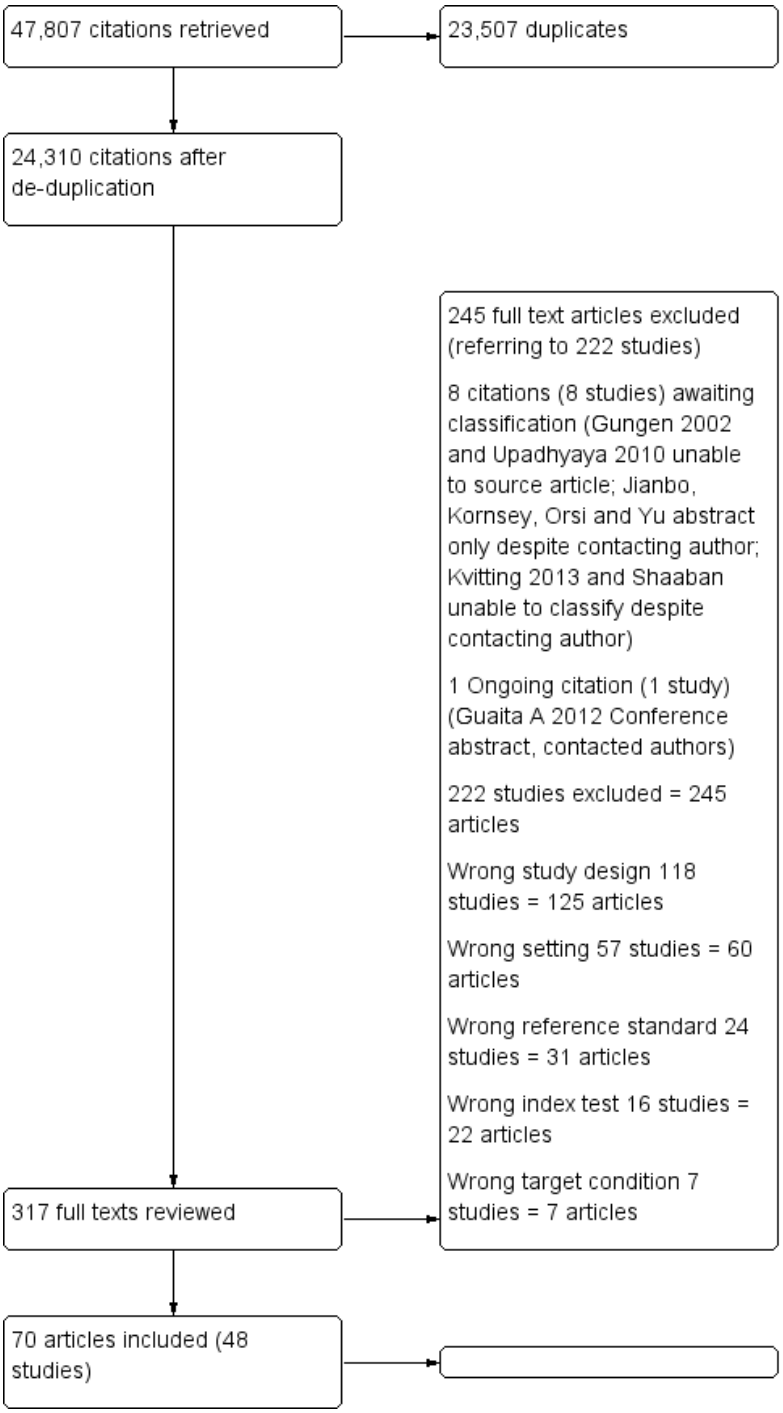
Figure 2. PRISMA Flow diagram of included studies.



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Data extraction and management

Two senior authors simultaneously extracted data on study characteristics and 2 x 2 data directly into Review Manager (RevMan 2014). We resolved disagreements by reaching consensus with a third, senior author.

Assessment of methodological quality

We assessed the risk of bias of each study using the QUADAS-2 tool in duplicate (Whiting 2011), as recommended by Cochrane (see Appendix 4 for QUADAS 2 statements and Appendix 5 for anchoring statements). The 'Assessment of methodological quality table' helps the reader to evaluate the strength of evidence to support the diagnostic accuracy of the MMSE.

Statistical analysis and data synthesis

We expected the diagnostic accuracy of the MMSE to differ between studies based in community and in primary care settings (and particularly in primary care participants selected on the basis of memory symptoms), and we planned to conduct separate analyses in the four potential study populations (see Types of studies above). We also planned to conduct separate analyses as required for each subtype of dementia.

For all included studies, the data in the 2 x 2 tables (showing the binary test results cross-classified with the binary reference standard) was used to calculate the sensitivities and specificities, with 95% confidence intervals. We present a summary of the included studies in Table 1 and Table 2. If studies reported more than one cut point, we presented the findings for all cut points reported.

In our main analysis, we performed meta-analyses on pairs of sensitivity and specificity, stratified by setting (community and primary care) using the HSROC method, using only one estimate from each study (Macaskill 2010). Where reported, this was the standard MMSE cut point of 23/24, where 24 indicates normal cognition, and where unreported, we used either the only estimate that was reported, or the best estimate (from the top lefthand corner of the study ROC curve, acknowledging that this may overestimate diagnostic accuracy in that study). We used Stata software (Stata) to perform the analysis and used the data to plot the summary ROC curve. We then used a bivariate random-effects model approach based on pairs of sensitivity and specificity (Chu 2006; Macaskill 2010; Reitsma 2005) to analyse the diagnostic accuracy at specific cut points in community-based studies, where there appeared to be consensus that these were commonly reported cut points (24 and 25 indicating normal and MMSE adjusted for education).

Investigations of heterogeneity

We investigated heterogeneity in the first instance through visual examination of forest plots of sensitivities and specificities. We prespecified factors that would potentially contribute to heterogeneity and attempted to adjust for these in the meta-analysis for average age of participants (in categories: 65 to 74 years, 75 to 84 years, 85 to 94 years, 95 years or more, unclear), sex, conduct of the test (in categories: specialist, trained non-specialist, or unclear) and reference standard. We used likelihood ratio tests to compare the fit of candidate models when assessing the effect of a covariate on test performance (Macaskill 2010).

Sensitivity analyses

We planned to perform sensitivity analyses to determine the effect of excluding studies deemed to be at high risk of bias. However, as studies were generally at low risk of bias - no study had more than two of four QUADAS-2 items assessed as having a high risk of bias - we did not do this as we did not pre-specify a point at which we would deem a study to be at overall 'high risk of bias'.

Assessment of reporting bias

Quantitative methods for exploring reporting bias are not well established for studies of diagnostic test accuracy (DTA) (Bossuyt 2013)

RESULTS

Results of the search

The search yielded 47,807 records, and 24,310 remained after removing duplicates (Figure 2). We reviewed the full text of 317 records (referring to 270 studies) and excluded 245 (referring to 222 studies), most commonly because of ineligible study design. We were unable to classify eight records because they were only available as abstracts and we could not obtain sufficient information about them despite attempting to contact authors (Gungen 2002; Jianbo 2013; Kornsey; Kvitting 2013; Orsi; Shaaban 2013; Upadhyaya 2010; Yu 2012). We found one ongoing study that had no results on diagnostic accuracy (Guiata 2012). We attempted to contact the authors of 17 articles, received replies from the authors of 10 and were able to include additional unpublished data from one study (Carnero-Pardo 2013). We included 70 articles, referring to 48 studies, in our synthesis. Table 1 and Table 2 give details of the studies in the community and primary care, respectively. Of the 48 studies that we reviewed, we were able to perform meta-

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analysis on 28 community-based studies (44 articles) and 6 studies in primary care (8 articles). Of the 28 community studies that we included in the meta-analysis, 7 reported accuracy estimates for level of education (referred to as 'education adjusted') and 21 reported accuracy estimates at various cut points. We could not include the remaining 14 community studies in the meta-analysis because paired 2 x 2 data was not available despite contacting authors. However, we include them in this report for transparent reporting, because we believe 2 x 2 data should exist based on the study design and characteristics. Two of the six studies in primary care were conducted in symptomatic people, selected to the study on the basis of a reported concern about cognition(Carnero-Pardo 2013; Cruz-Orduna 2012), whereas the other four primary care studies and all of the community studies were in asymptomatic people, for whom reported cognitive difficulty was not a criterion for inclusion in the study. Studies reported the target condition as all-cause dementia syndrome, so we could not analyse diagnostic accuracy by subtype.

In the meta-analysis there were 12,110 participants in community studies and 1681 participants in primary care studies. For community-based studies we were able to perform meta-analysis using the bivariate method at cut points of 24 and 25 and in studies that adjusted accuracy estimates for level of education (referred to as 'education adjusted'). The Summary of findings presents these results. For studies in primary care, we could not perform meta-analysis using the bivariate method due to heterogeneity in the cut points reported, and so we cannot report a summary sensitivity and specificity. We include further details of the studies, including the design, sampling, reference standard and population, in the Characteristics of included studies.

We found one prior systematic review on the same topic, which included five studies that were excluded by our methods (Mitchell 2009). Table 3 presents the details of these studies. Cullen 2005 and Huppert 2005, two of the five studies that we excluded, used AGECAT as the reference standard (Copeland 1986), and the other three studies used CAMDEX (Roth 1986). Two of the studies used a cut point of 22 to determine normal cognition (Brayne 1989; Clarke 1991), one used a cut point of 23 (Huppert 2005), and two used a cut point of 24 (Cullen 2005; O'Connor 1989).

Methodological quality of included studies

We used QUADAS-2 to help determine the risk of bias for each study in order to determine the confidence that patients and clinicians can have in the results of each study (Appendix 4; Appendix 5). We summarise the main results below and in Figure 3 and Figure 4.

Figure 3. Risk of bias and applicability concerns graph: review authors' judgements about each domain presented as percentages across included studies

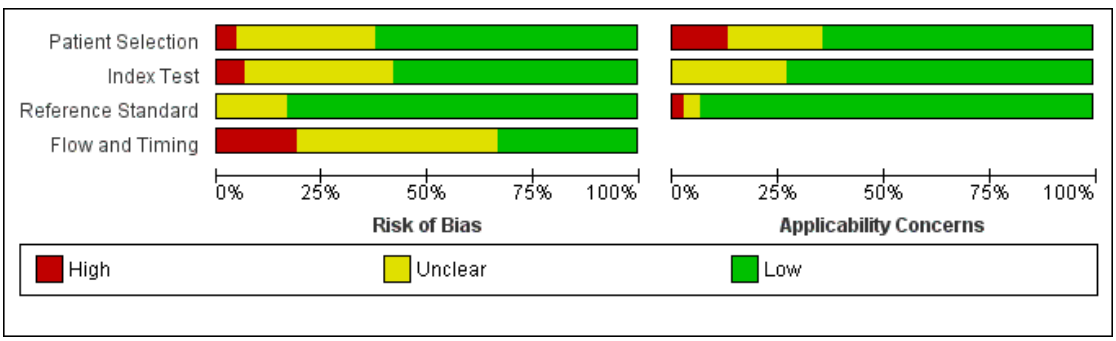

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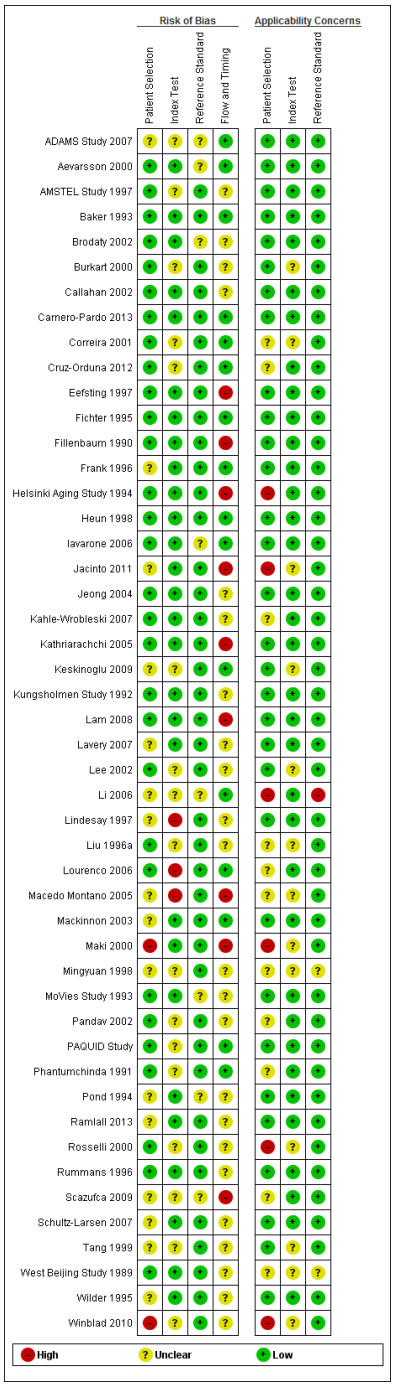
Figure 4. Risk of bias and applicability concerns summary: review authors' judgements about each domain for each included study



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We judged Maki 2000 and Winblad 2010 to be at high risk of bias in the patient selection domain because Maki 2000 excluded people who lived alone and Winblad 2010 appeared to exclude people who were known to have dementia. We considered three studies to be at high risk of bias in the index test domain because it appeared that investigators did not specify the cut point before the analysis (Lindesay 1997; Lourenco 2006; Macedo Montano 2005). We identified nine studies that we considered to be at high risk of bias regarding flow and timing because we had concerns about partial verification of the index test: Eefsting 1997 administered the reference test to a proportion of each scoring band on the MMSE; Fillenbaum 1990 administered the reference standard to a sample of participants; Helsinki Aging Study 1994 only administered a reference standard to people who were diagnosed with possible dementia on the basis of an assessment by a GP; Jacinto 2011 did not describe the flow and timing; Kathriarachchi 2005, Lam 2008 and Macedo Montano 2005 partially verified the diagnosis with a sample of participants, but it was not clear how they selected the sample; Scazufca 2009 appeared to exclude people who were unable to answer items in the MMSE and said that 81 people were not approached but did not explain why. Finally, Maki 2000 administered the reference standard to a sample of people, but we could not reconcile the figures that were stated in the paper.

We assessed most studies as being applicable to the review question, though we had concerns that the selection of participants in six might reduce their applicability (Helsinki Aging Study 1994; Jacinto 2011; Li 2006; Maki 2000; Rosselli 2000; Winblad 2010). We had high concern that Li 2006 used a target condition (mild cognitive impairment and dementia) that was not applicable to our review question and were unable to include data on diagnostic accuracy from this study. As studies were generally at low risk of bias - no study had more than two of four QUADAS-2 items that were assessed as high risk of bias - we did not exclude studies from the meta-analysis based on the risk of bias as we did not pre-specify a point at which we would deem a study to be at overall 'high risk of bias'.

Findings

Table 1 and Table 2 show that the accuracy of the MMSE for diagnosing dementia was reported at 18 cut points (MMSE score 10, 14 to 30 inclusive) in the community and 10 cut points (MMSE score 17 to 26 inclusive) in primary care studies. Summary of findings presents the summary diagnostic accuracy in community studies: sensitivity 0.85 (95% confidence interval (CI) 0.74 to 0.92), specificity 0.90 (95% CI 0.8 to 0.95) at a cut point of 24 (15 studies); sensitivity 0.87 (95% CI 0.78 to 0.93), specificity 0.82 (95% CI 0.65 to 0.92) at a cut point of 25 (10 studies); and sensitivity 0.97 (95% CI 0.83 to 1.00), specificity 0.70 (95% CI 0.50 to 0.85) when adjusted for education (7 studies). In primary care studies, each cut point was reported by a maximum of three studies, and we could not provide a summary of sensitivity and specificity.

Community studies

In community studies the accuracy of the MMSE for the diagnosis of dementia was available for 18 cut points (10, 14 to 30 inclusive) and also adjusted for education. At a cut point of 10, accuracy was sensitivity 0.11 (95% CI 0.00 to 0.48), specificity 0.95 (95% CI 0.93 to 0.97) (Phantumchinda 1991), and at a cut point of 30 accuracy was sensitivity 1.00 (95% CI 0.98 to 1.00), specificity 0.00 (95% CI 0.00 to 0.01) (Kahle-Wrobleski 2007). Figure 5 presents the summary ROC curve for community studies in the main analysis, including all 21 studies that reported 2 x 2 data, and Figure 6 presents the linked forest plot.

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Figure 5. Summary ROC Plot of analysis 2 main community

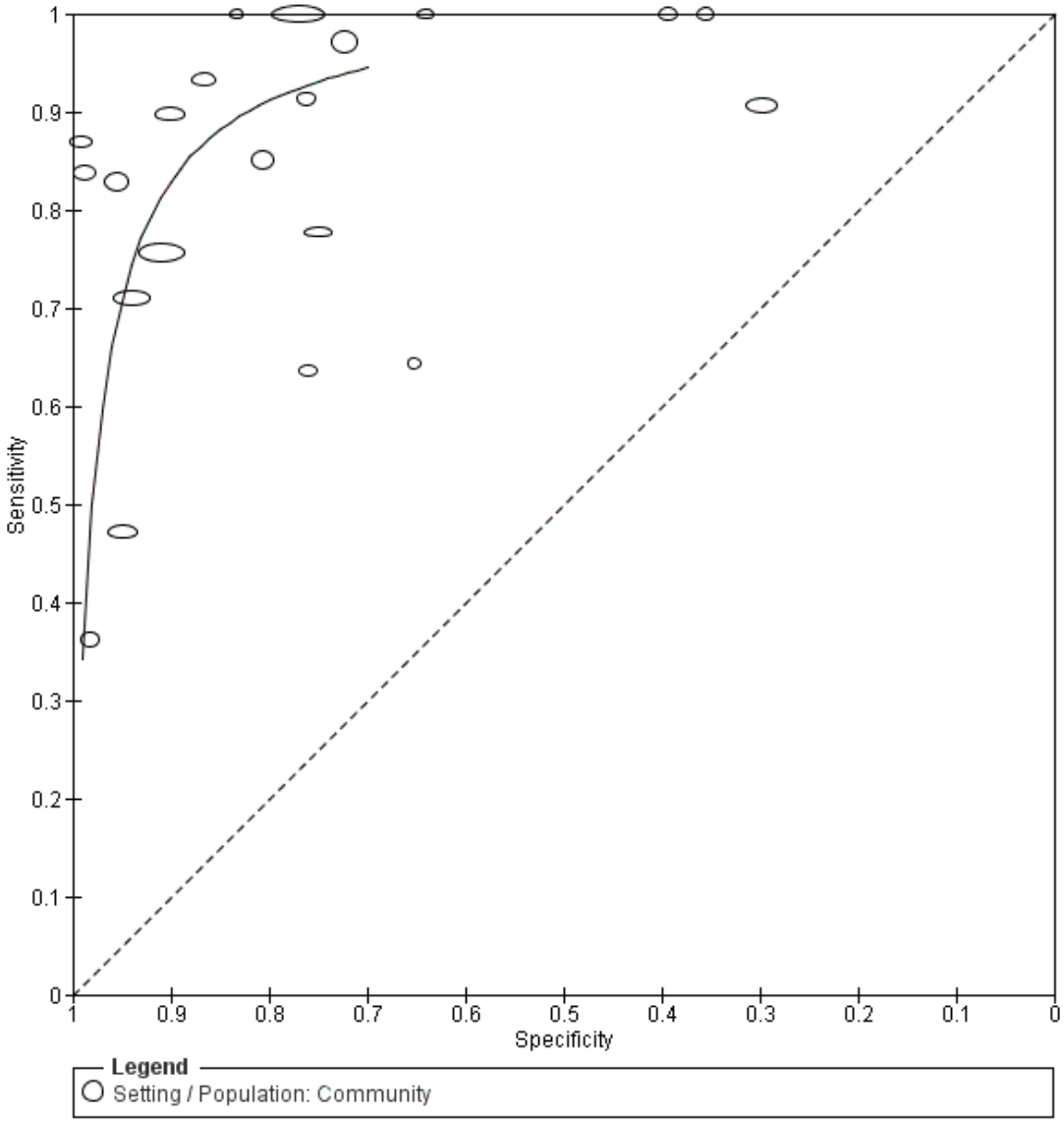

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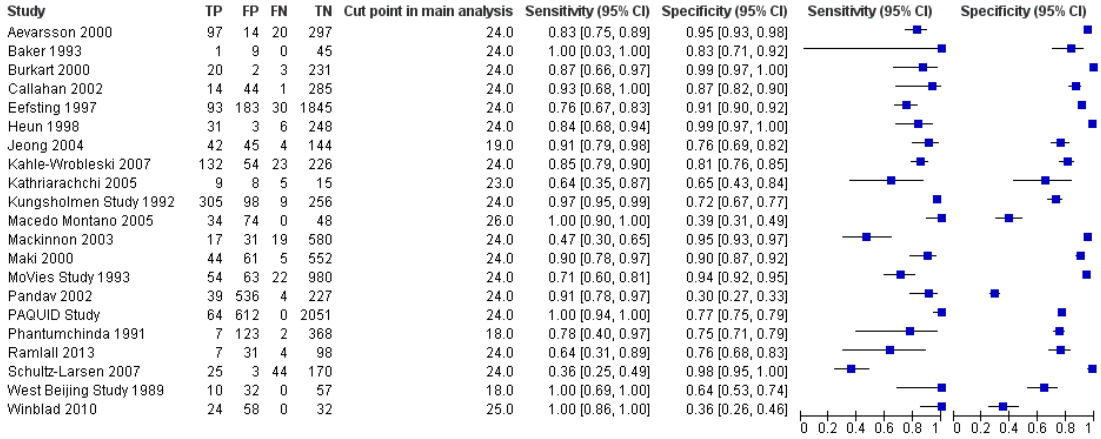
Figure 6. Forest plot of analysis 2 Main community



We were able to include seven community studies in the meta-analysis of diagnostic accuracy in studies whose original investigators adjusted the MMSE for education. We present the summary ROC in Figure 7 and the forest plot in Figure 8. The pooled estimate for the diagnostic accuracy was sensitivity 0.97 (95% CI 0.83 to 1.00), specificity 0.70 (95% CI 0.50 to 0.85). We were able to include 15 studies in the meta-analysis of diagnostic accuracy at a cut point of 24; Figure 9 presents the summary ROC curve and Figure 10, the forest plot; the pooled estimate for the diagnostic accuracy was sensitivity 0.85 (95% CI 0.74 to 0.92), specificity 0.90 (95% CI 0.82 to 0.95). We were able to include 10 studies in the meta-analysis of diagnostic accuracy at a cut point of 25; Figure 11 presents the summary ROC and Figure 12, the forest plot. The pooled estimate for the diagnostic accuracy was sensitivity 0.87 (95% CI 0.78 to 0.93), specificity 0.82 (95% CI 0.65 to 0.92).

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Figure 7. Summary ROC plot of analysis 3 community, education adjusted. The black filled dot indicates the summary point estimate of diagnostic accuracy, the smaller dotted bubble indicates the 95% confidence interval around the summary point (containing the 'true value' within that region 95% of the time on the basis of the available data) and the larger dashed bubble indicates the 95% prediction region (containing results from a new future study 95% of the time).

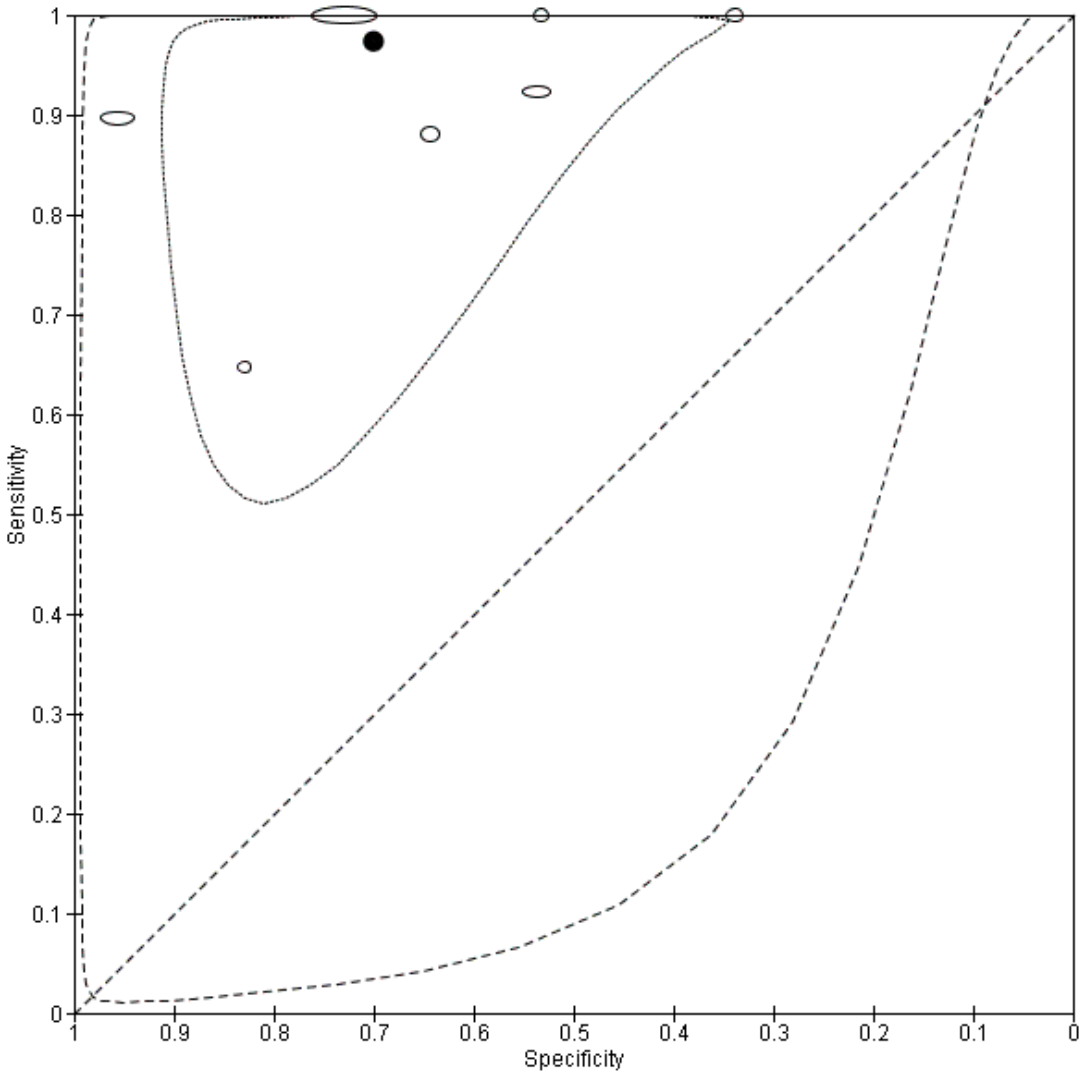

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Figure 8. Forest plot of analysis 3 MMSE community, education adjusted

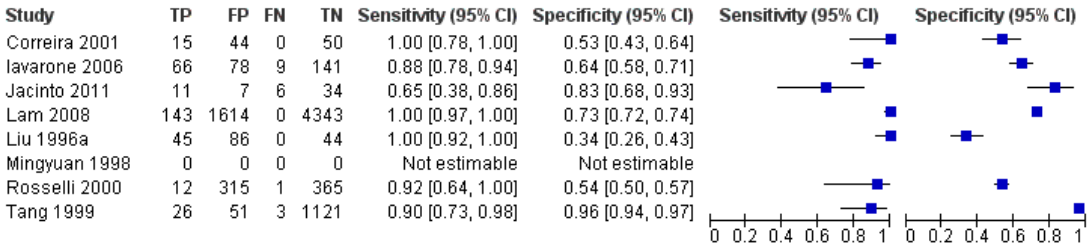

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Figure 9. Summary ROC plot of analysis 4 MMSE at 24 normality (23/24). The black filled dot indicates the summary point estimate of diagnostic accuracy, the smaller dotted bubble indicates the 95% confidence interval around the summary point (containing the 'true value' within that region 95% of the time on the basis of the available data) and the larger dashed bubble indicates the 95% prediction region (containing results from a new future study 95% of the time).

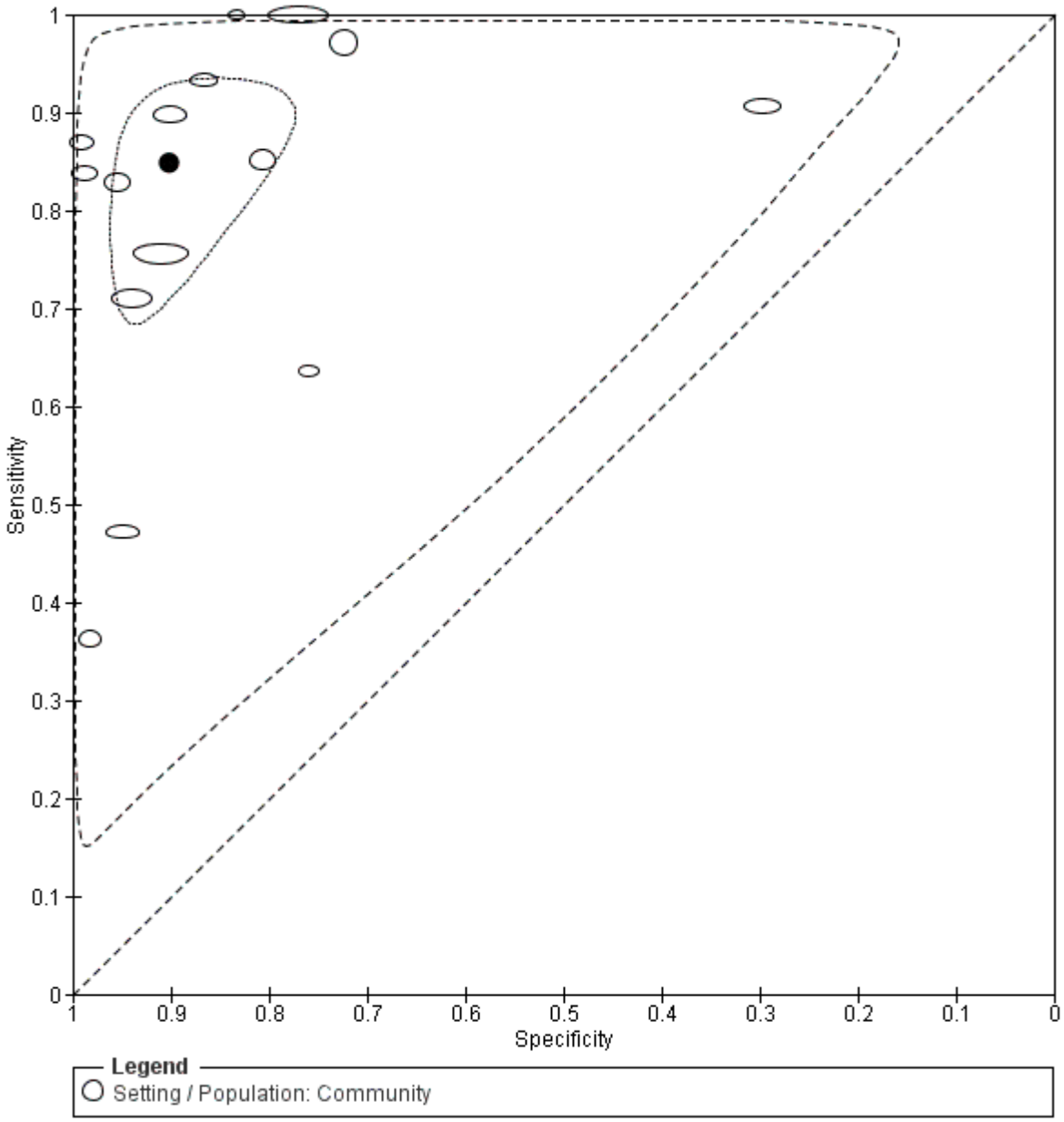

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Figure 10. Forest plot of analysis 4 MMSE at 24 normality (23/24).

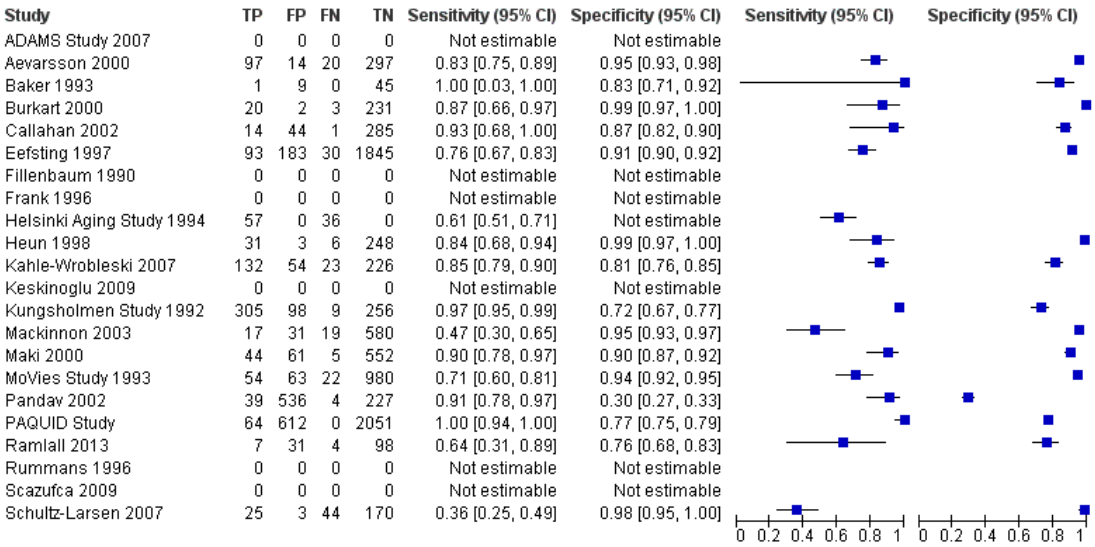

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Figure 11. Summary ROC plot of analysis 5 MMSE at 25 normality. The black filled dot indicates the summary point estimate of diagnostic accuracy, the smaller dotted bubble indicates the 95% confidence interval around the summary point (containing the 'true value' within that region 95% of the time on the basis of the available data) and the larger dashed bubble indicates the 95% prediction region (containing results from a new future study 95% of the time).

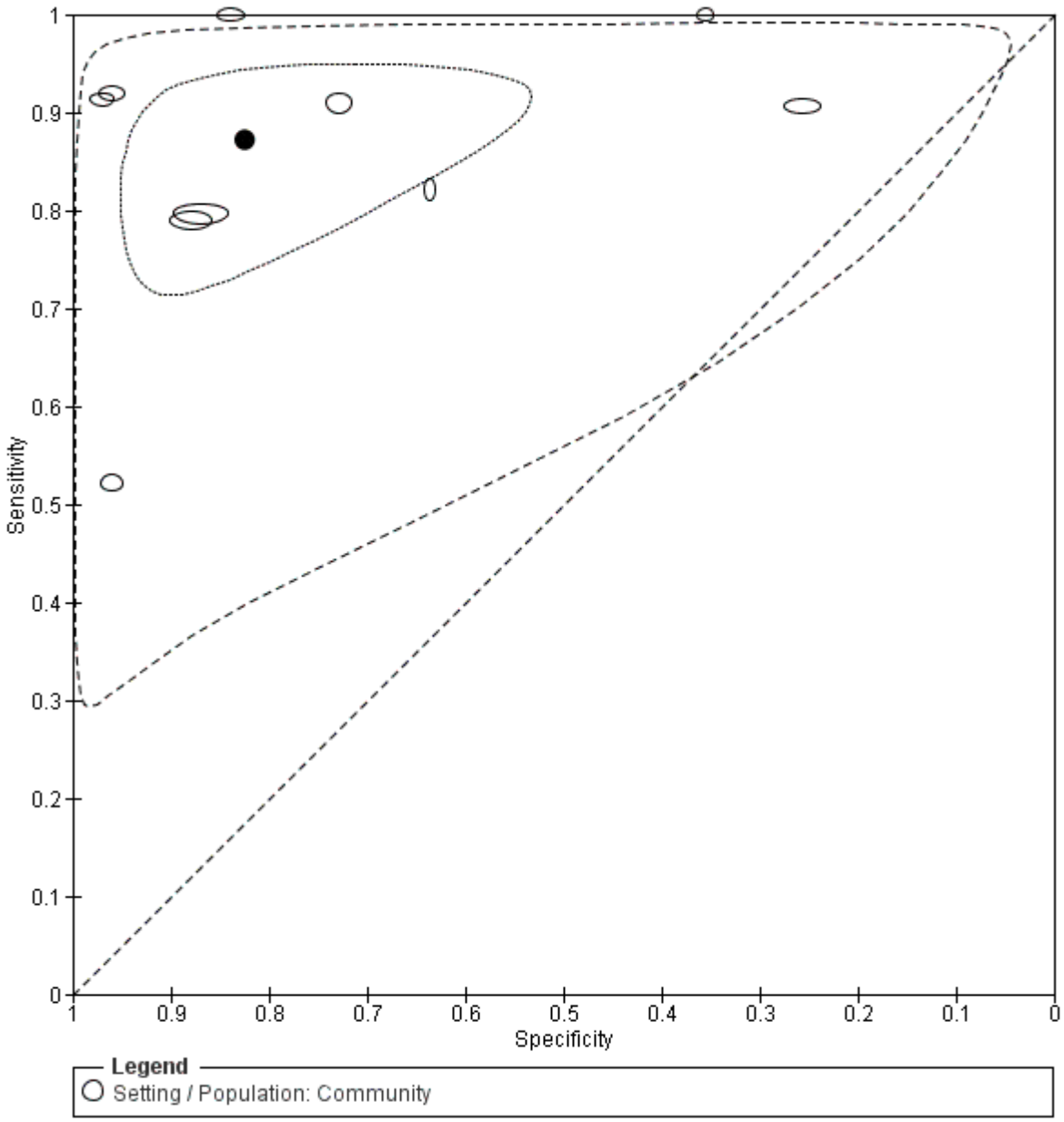

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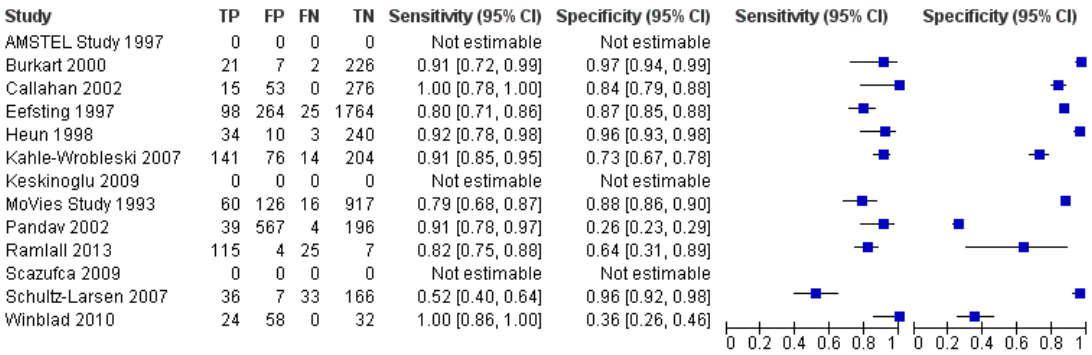
Figure 12. Forest plot of analysis 5 MMSE at 25 normality.



Primary care studies

In symptomatic people the accuracy of the MMSE for the diagnosis of dementia was available for 9 cut points (17 to 25 inclusive). At a cut point of 19, accuracy was sensitivity 0.80 (95% CI 0.52 to 0.96), specificity 0.86 (95% CI 0.80 to 0.91) in Cruz-Orduna 2012 and sensitivity 0.88 (95% CI 0.79 to 0.95), specificity 0.87 (95% CI 0.82 to 0.91) in Carnero-Pardo 2013 .Carnero-Pardo 2013 reported accuracy for cut points from 17 (sensitivity 0.70 (95% CI 0.59 to 0.80), specificity 0.93 (95% CI 0.89 to 0.96)), to 25 (sensitivity 1.00 (95% CI 0.95 to 1.00), specificity 0.38 (95% CI 0.32 to 0.44)). At the traditional cut point of 24, the accuracy was sensitivity 1.00 (95% CI 0.95 to 1.00), specificity 0.46 (95% CI 0.40 to 0.52).

In asymptomatic people the accuracy of the MMSE for the diagnosis of dementia was available for 9 cut points (18 to 26 inclusive). Lourenco 2006 reported that at a cut point of 18, accuracy was sensitivity 0.35 (95% CI 0.24 to 0.46), specificity 0.94 (95% CI 0.90 to 0.97), and at a cut point of 26 the accuracy was sensitivity 0.90 (95% CI 0.81 to 0.95), specificity 0.50 (95% CI 0.43 to 0.56). At the traditional cut point of 24, Lourenco 2006 found a sensitivity of 0.65 (95% CI 0.59 to 0.72) and specificity of 0.65 (95% CI 0.59 to 0.72), while Pond 1994 reported sensitivity 0.95 (95% CI 0.92 to 0.97) and specificity 0.95 (95% CI 0.92 to 0.97). Figure 13 presents the summary ROC curve for primary care studies and Figure 14, the forest plot.

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Figure 13. Summary ROC plot of analysis 1 Main analysis primary care

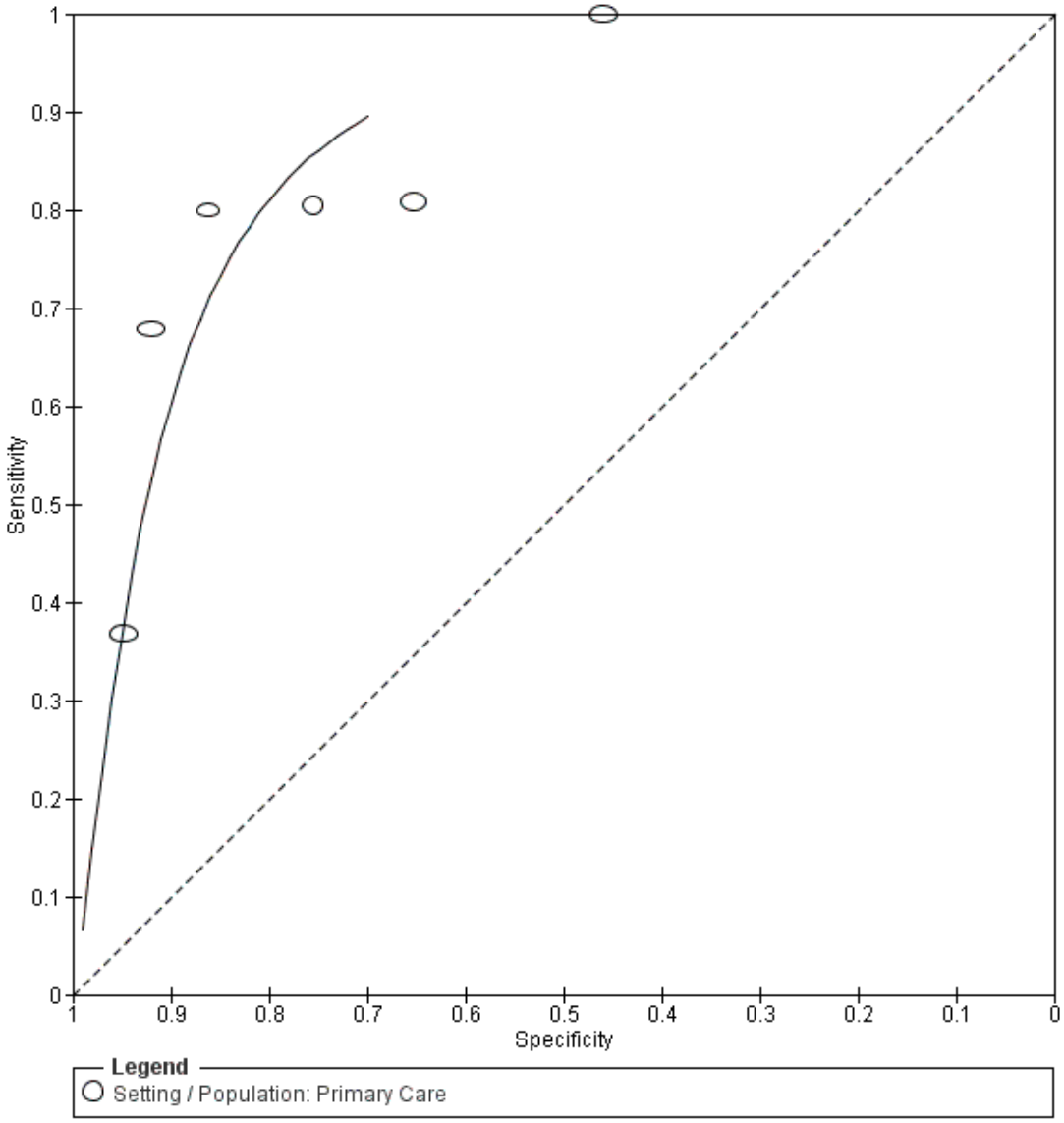

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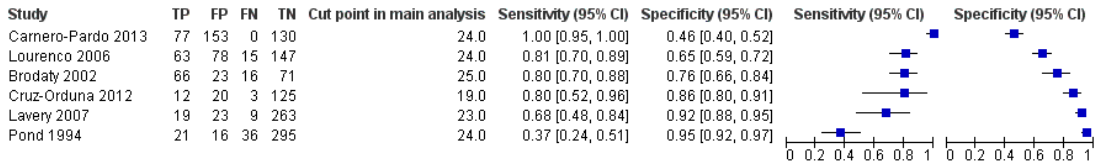
Figure 14. Forest plot of analysis 1 Main analysis primary care



Heterogeneity

We used additional models to explore potential heterogeneity in the diagnostic accuracy of the main analysis by age, sex, conduct and reference standard. Additionally we attempted to evaluate heterogeneity by education and mean MMSE score in the sample, but this was not possible because these data were poorly reported in the original studies. We found no evidence against the null hypothesis of no heterogeneity for age (P = 1.00 likelihood ratio (LR) Chi $^2(4) = -9.49$), sex (P = 1.00 LR $Chi^2(4) = -20.68$) or conduct (P = 0.0647 LR $Chi^2(4) = 8.85$). There was some evidence against the null hypothesis of no heterogeneity by reference standard (P = 0.0342 LR $Chi^2(8) = 16.63$).

Sensitivity analyses

We did not perform any sensitivity analyses.

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Summary of findings

What is the accuracy of the Mini Mental State Examination (MMSE) for diagnosing current dementia compared to clinical diagnosis of dementia?

Index test: Mini Mental State Examination (MMSE) administered to the patient. We restricted inclusion to the original 30 item MMSE but did not restrict by language
Reference test: clinical diagnosis of dementia made using any recognised classification system
Studies: cross-sectional studies but not case-control studies
Limitations: there were too few studies to perform meta-analysis at each cut point. We could not perform bivariate meta-analysis on studies in primary care as there were too few
Population: adults resident in the community
Setting: community

Test	Summary accuracy (95% CI)	No. of participants (studies); median (IQR)	Dementia prevalence median (IQR)	Quality, Implications and Comments
MMSE at cut point 24 indicating normal	Sensitivity 0.85 (0.74, 0.92) specificity 0.90 (0.82, 0.95)	10969 (15); 435 (272 to 737)	7.4% (5.5% to 20.1%)	Studies were generally at low risk of bias (none were at high or unclear risk in more than 1 domain) In a group of 1000 people where 7 have dementia, 105 test positive, 6 of whom have dementia, and 895 test negative, 1 of whom has dementia A large number of people would need to be evaluated further to identify the people with dementia. 1 person with dementia is 'missed'
MMSE at cut point 25 indicating normal	Sensitivity 0.87 (0.78, 0.93) specificity 0.82 (0.65, 0.92)	5894 (10) 316 (246 to 713)	8.4% (6.0% to 19.0%)	1 study was high risk for patient selection and unclear risk in 2 others (Winblad 2010). 1 other study was high risk in patient flow (Eefsting 1997). Otherwise studies were at low risk of bias. In a group of 1000 people where 8 have dementia, 186 test posi-

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					tive, 7 of whom have dementia, and 814 test negative, 1 of whom has dementia Impact is similar to use of the 24 cut point but more people require further evaluation
MMSE at cut point adjusted for education	Sensitivity specificity	0.97 (0.83, 1.00) 0.70 (0.50, 0.85)	8442 (7) 294 (120 to 947)	13.8% (2.4% to 27.4%)	2 studies were at high risk of bias for patient flow (Jacinto 2011; Lam 2008), otherwise studies were at low or unclear risk of bias. In a group of 1000 people where 14 have dementia, 309 test positive, 14 of whom have dementia, 691 test negative, none of whom have dementia Many people need to be further evaluated to identify the people who have dementia but everybody with dementia is identified

CI: confidence interval; **IQR**: interquartile range.

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DISCUSSION

Summary of main results

In community studies of asymptomatic people, with a cut point of 24 indicating normal cognition, the MMSE had pooled diagnostic accuracy of sensitivity 0.85 (95% CI 0.74 to 0.92), specificity 0.90 (95% CI 0.82 to 0.95). The pooled diagnostic accuracy at a cut point of 25 was similar, whereas the MMSE adjusted for education was better for screening, at the cost of more false positives, with sensitivity 0.97 (95% CI 0.83 to 1.00) and specificity 0.70 (95% CI 0.50 to 0.85). In primary care, a single study of symptomatic people reported that a cut point of 17 had higher specificity (0.93 95% CI 0.89 to 0.96) than a cut point of 24 (0.46 95% CI 0.40, 0.52), with some additional false negatives as the sensitivity fell from 1.00 (95% CI 0.95 to 1.00) to 0.70 (95% CI 0.59 to 0.80) (Carnero-Pardo 2013).

The risk of bias in the included studies is summarised in Figure 3. We generally had low concern about bias in the included studies. There were some differences between studies, but we found no evidence against the null hypothesis of no statistical heterogeneity by age, sex, or conduct of the index test. We found some evidence of heterogeneity by reference standard, but most of the studies used the clinical DSM definition for the target condition of all-cause dementia. Some of the confidence intervals around the point estimates are wide, which indicates some uncertainty in our results because of the limitations of the underlying data.

Strengths and weaknesses of the review

We used a comprehensive and sensitive search strategy that yielded substantially more results than a similar, earlier review that found only 775 articles and included a total of 21 studies in any setting (Mitchell 2009). We followed our pre-specified peer-reviewed protocol, which did not specify CAMDEX, CERAD or AGECAT as appropriate reference standards. Consequently we excluded studies that used these reference standards. We found few studies in primary care that used the references standards we specified and even fewer in participants selected on the basis of symptoms (symptomatic primary care). We found sufficient studies to perform meta-analysis of test accuracy and to explore heterogeneity, but our evaluation was limited by poorly reported factors (education and mean MMSE score). On the other hand, assessing heterogeneity by factors that are not measured at the study level (e.g. education, severity of diagnosis or subtype diagnosis) is generally not recommended (Bossuyt 2013). We did not use a separate form (as we stated in the protocol), but we extracted data directly into RevMan after we set up the file using a set of pilot studies, as we pre-specified (RevMan 2014). This was because we were concerned about introducing errors when copying data from an Access database into RevMan given the large number of studies. At least two authors, and usually three, performed data extraction and quality assessment, checking the accuracy of the extracted data in real time.

Applicability of findings to the review question

We consider that our findings are likely to be applicable to our review question. We had aimed to evaluate the strength of evidence for the accuracy of the MMSE for diagnosing Alzheimer's disease dementia and other dementias, but studies only reported all-cause dementia, so we were not able to evaluate the diagnostic accuracy by subtype. Despite this, for clinicians and patients in primary care and community settings, the most important clinical question determining intervention and follow-up is often, 'Does this person have a dementia now?', and our review addresses this.

AUTHORS' CONCLUSIONS

Implications for practice

In this section we present results using natural frequencies, but these do not take account of the confidence intervals and uncertainty in our results and so should be interpreted with caution.

If clinicians would like to use the MMSE in primary care to rule in a diagnosis of dementia in a symptomatic person, there is evidence from one study that a cut point of 17 to indicate normal cognition would have higher specificity than a traditional cut point of 24, with a slightly lower sensitivity: the median prevalence of dementia in primary care studies was 18.5%, so - rounding up to 20% for the sake of convenience - of 1000 people in this setting, with 200 expected to have dementia at a cut point of 17 indicating normal, clinicians could expect 196 to test positive, of whom 140 (71%) would truly have dementia; 804 would test negative, of whom 744 (93%) would not have dementia (Carnero-Pardo 2013). If the test were being used to identify anybody who might have dementia regardless of concern about cognition, then there is evidence from seven community-based studies that the accuracy of the MMSE adjusted for education has a higher sensitivity than when a cut point of 24 or 25 is used (based on the meta-analytical estimates of 15 studies and 10 studies, respectively), although the specificity is lower and consequently there are more false positives, and this might mean unnecessary further evaluation for some people. Clinicians and patients can be confident that the MMSE is likely to be of some diagnostic value at cut points of 24, 25 and adjusted for education, though the uncertainty in the estimates does not allow us to confidently choose between these three approaches.

We consider that the evidence we present supports the use of the MMSE as part of a diagnostic evaluation for dementia, but it should not be used in isolation to confirm or exclude disease. Our

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review allowed for a diagnosis of dementia at any stage of disease; we did not explore heterogeneity by disease spectrum, and to do so would have been challenging and not recommended (Bossuyt 2013). However, we would advocate considering carefully how our results apply in the clinical context. When considering the studies that reported the highest cut point in asymptomatic people in the community and the lowest cut point in symptomatic people in primary care, then based on Burkart 2000 at a cut point of 29 indicating normal cognition in a sample of 1000 asymptomatic people in the community where 65 have dementia, we would expect that 367 people would have a normal result, of whom 2 would have dementia. Conversely, based on Carnero-Pardo 2013, at a cut point of 17 indicating normal cognition in a sample of 1000 people in primary care, where 200 have dementia, we would expect that 196 test positive, of whom 56 would not have dementia. Thus, a diagnosis of dementia may still be possible even with high (normal) scores on MMSE, and people may not have dementia even with low (abnormal) MMSE scores. The use of the MMSE in the community will usually be followed up by further clinical evaluation of people who have abnormal scores.

Implications for research

The MMSE is now protected by copyright and is likely to be used less in clinical practice in the future than it has been in the past, but these data may be useful for research studies. We were surprised to find so few studies in symptomatic people. Original study authors did not optimally report factors that might affect performance of the test.

Many of the studies that we included, particularly those in the community, are screening studies (see Clinical pathway). An ageing population is prompting policymakers to consider changes to the traditional clinical pathway, and in the future non-specialist clinicians in primary care may be responsible for diagnosing straightforward cases of dementia (Barrett 2014). However, we found very few studies to inform policymaking in this area.

We recommend that future work evaluate the diagnostic accuracy of tests in the context of the diagnostic pathway experienced by the patient: that is, allowing for the presence or absence of subjective memory problems, symptoms and the view of caregivers and clinicians. We also suggest that in addition to testing accuracy alone,investigators report how undergoing the MMSE (or other similar cognitive test) changes outcomes that are relevant to patients and clinicians, such as time to diagnosis, initiation of treatment or care package, subsequent additional testing and place of care. We advocate the use of STARDEM reporting criteria to aid transparent reporting of future diagnostic test accuracy studies with dementia as the target condition (Noel-Storr 2014).

ACKNOWLEDGEMENTS

We thank the authors of original manuscripts who replied to correspondence and provided additional data.

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* *Indicates the major publication for the study*

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

ADAMS Study 2007

Study characteristics	
Patient sampling	The ADAMS study sample came from the nationally representative Health and Retirement Study (HRS) as sample frame. From the larger HRS sample, a random subsample of 1770 individuals aged 70 or over was selected for participation in the ADAMS, with the goal of obtaining clinical assessments on about 850 individuals. In order to ensure a sufficient number of respondents across the full range of cognitive ability, investigators stratified the sample based on cognitive status. 5 cognitive strata (ranging from 'low functioning' to 'high normal') were defined based on respondents' performance on the cognitive measures in the most recent HRS interview (either 2000 or 2002, depending on the timing of recruitment into the ADAMS). Investigators used scores on the full set of HRS cognitive tests (ranging from 0 to 35 points) to classify self-respondents, and scores on the IQCODE were used to classify proxy respondents. The cognitively normal group was further stratified by age (70-79 versus $\geq$ 80) and sex in order to ensure adequate numbers in each of these subgroups The original HRS sample consisted of individuals born between 1931 and 1941, inclusive. This sample came from a screening of 69,336 households that was conducted in 1992. That sample of households was generated using a multi-stage, clustered area probability frame. The second sample was generated for what began as a separate study: Asset and Health Dynamics among the Oldest Old (AHEAD). This sample consists of individuals born in 1923 or before. Those born between 1914 and 1923, and about half of those born in 1913 or before, were identified through the same household screening used to identify the original HRS sample. The other half of those born in 1913 or before were identified using the Medicare enrolment files maintained by the Health Care Financing Administration (HCFA, since renamed the Centres for Medicare & Medicaid Services, or CMS). In 1998, the HRS and AHEAD studies were merged, with a single interview schedule 856 adults were sampled from ADAMS, however 155 of these were excluded due to not completing the MMSE
Patient characteristics and setting	Participants included 509 white, 124 African Americans, and 68 Latinos (> 70 years old) from the Aging, Demographics, and Memory Study who completed the MMSE and FOME. There were 314 men, average age 80.5 years. Average education was 9.2 years. Average MMSE score was 23
Index tests	MMSE, non-validated Spanish versions where necessary.
Target condition and reference standard(s)	Dementia diagnosed according to DSM-IV. Participants consented to a 3-4 h structured assessment conducted in-home, including a medical examination with a nurse and a neuropsychological battery with a trained psychometrician A panel of 3 expert scientists, including a neurologist, cognitive neuroscientist, and geropsychiatrist determined the participants' initial DSM-IV cognitive status based on the in-home diagnostic evaluation, which assessed several cognitive domains The final cognitive status was made by a consensus panel of experts based on a review of the information collected through the neuropsychological, medical, and neurological assessment measures We assess this as meaning that not all 701 participants were clinically evaluated by a specialist

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ADAMS Study 2007 (*Continued*)

Flow and timing	All participants who received MMSE also received the reference standard. Note that this was due to the way that the sample was selected and we have accounted for this in the QUADAS-2 item regarding inappropriate exclusions
Comparative	
Notes	Participants were excluded if they couldn't/hadn't completed the MMSE We contacted the authors to ask them to provide 2 x 2 data, unstratified by ethnicity, but they were unable to do this. The diagnostic accuracy stratified by ethnicity was: For white participants, normal vs. dementia: sensitivity 0.87, specificity 0.98 (no confidence intervals; cut point 24 indicating normal; 509 participants, 129 with dementia) For African American participants, normal vs. dementia: sensitivity 0.92, specificity 0.84 (no confidence intervals; cut point 21 indicating normal; 124 participants, 37 with dementia) For Latino participants, normal vs. dementia: sensitivity 0.92, specificity 0.84 (no confidence intervals, cut point 21 indicating normal; 68 participants 13 with dementia)

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	No		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Unclear		
			Low
DOMAIN 3: Reference Standard			

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ADAMS Study 2007 (*Continued*)

Is the reference standards likely to correctly classify the target condition?	Unclear		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Aevarsson 2000

Study characteristics			
Patient sampling	Community sample of adults on census		
Patient characteristics and setting	All 85-year olds, in Goteborg, Sweden, who were registered for census, were invited for survey and a systematic subsample (N = 494) were clinically evaluated and comprise this diagnostic test accuracy study. 1986, 1987		
Index tests	Swedish MMSE		
Target condition and reference standard(s)	Dementia. DSM-III-R criteria and subtypes - possibility of incorporation bias as MMSE formed a part of the reference standard		
Flow and timing	Information collected at 1 interview, but informant interview considered separately to examination		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**

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Aevarsson 2000 (*Continued*)

DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

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AMSTEL Study 1997

Study characteristics			
Patient sampling	Subjects were participants in AMSTEL 2 phase population study. 4051 participants aged 65-84 were recruited. The population base for the AMSTEL study included all individuals aged 65-84 who lived in Amsterdam and were registered with a GP. Within each practice a fixed proportion of respondents was randomly selected from each of four 5-year age strata (65-69, . . . 80-84)		
Patient characteristics and setting	64.2% women, average age 75.4, 8.2 years of education, mean MMSE score 26.9		
Index tests	Non-validated Dutch translation of MMSE		
Target condition and reference standard(s)	Dementia diagnosed according to DSM-III-R using CAMDEX as a framework		
Flow and timing	4051 participants had MMSE, in phase II everybody with an MMSE of < 22, an age stratified sample of people with MMSE scores > 22 were invited (N = 511). Those people were seen and assessed a median of 7 weeks (range 1-22) after the index test		
Comparative			
Notes	We were unable to include this in the meta-analysis. The marginal totals were 261 disease positives, 3790 disease negatives, 72 test positives. After several lots of correspondence with the authors, we were provided with some sensitivity and specificity data (for cut point 24 indicating normality this was sensitivity 0.69, specificity 0.47); however, it was not possible to reconcile the 2 sets of figures		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		

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AMSTEL Study 1997 (*Continued*)

Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Unclear		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	No		

Baker 1993

Study characteristics	
Patient sampling	The sample was drawn from 2 sites in San Antonio, Texas: a senior citizen housing complex and a senior centre. The senior housing complex was comprised of 72 apartments in 2-storey dwellings located in a section of the city that was predominantly African American. The senior citizen centre was located in the same area. In addition to providing hot meals, health screening programmes, and various community activities, it also provided the opportunity for volunteer activities
Patient characteristics and setting	The sample was African American and comprised 41 females and 14 men (75% female), mean age was 79. Mean MMSE 26
Index tests	MMSE

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Baker 1993 (*Continued*)

Target condition and reference standard(s)	Dementia diagnosed according to DSM-III-R		
Flow and timing	Reference standard was applied to all 55 participants within an average of 7 days (3 interviews were completed outside of this time-frame due to conflicting schedules)		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent	Yes		

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Baker 1993 (*Continued*)

study?			
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Brodaty 2002

Study characteristics	
Patient sampling	"Of 380 community-dwelling patients recruited by their GPs, 283 completed the study. Patients were included if they were aged 75 years or more regardless of cognitive status. To imitate usual practice, subjects aged 50 to 74 suspected of having a memory problem were also included. Patients were excluded if they resided in a nursing home; if they had a diagnosis of depression or delirium; or if poor English language abilities, sight, or hearing precluded testing "GPs were asked to administer the GPCOG (before subsequent refinement) and AMT to consecutive eligible patients and to contact an informant (by telephone or in person) who had known the patient for at least 5 years. Approximately 5 weeks later, a research psychologist visited the patient at home, administered the various instruments, including the CAMDEX and the GPCOG again, and, where possible, interviewed an informant."
Patient characteristics and setting	"There were no differences between participants diagnosed with dementia and those without dementia as regards gender (40.6% of the sample were male), relationship with informant (40.6% were spouses), living arrangements (87.6% lived in a private home and the others in retirement villages or hostels), or education (mean 9.4 years). Patients' overall mean age was 79.6 years (range 56-94); 32 patients (11.3%) were aged 50 to 75. Those diagnosed with dementia were older (mean 80.7 years) than those without dementia (79.1 years) and less likely to be living with an informant (71.1% and 82.9%, respectively)."
Index tests	"Psychologist-administered MMSE"
Target condition and reference standard(s)	Dementia as diagnosed according to DSM-IV
Flow and timing	"[D]iagnoses of dementia and delirium were established according to DSM-IV criteria on all 156 subjects suspected to be cognitively impaired (CAMCOG score < 85) and a random sample of 20 cognitively intact individuals (CAMCOG score > 84) (62.2% of all cases reviewed). No case was found to meet criteria for delirium."

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Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	No		
			Low
DOMAIN 4: Flow and Timing			

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Brodaty 2002 (*Continued*)

Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Burkart 2000

Study characteristics			
Patient sampling	Age-stratified random sample of 1305 subjects with over-sampling of advanced age, invited by letters and telephone		
Patient characteristics and setting	Community: 291 consented but only 256 completed tests n = 256 for analysis		
Index tests	MMSE (as part of SIDAM = Structured Interview for the Diagnosis of Dementia of the Alzheimer Type, Multi-infarct dementia and dementias of other aetiologies). SIDAM takes 28 minutes rather than MMSE 7 minutes (Zaudig 1991) Given by trained medical students		
Target condition and reference standard(s)	Dementia. ICD-10 and DSM-III-R		
Flow and timing	Medical students performed personal interviews. Psychiatrists made formal diagnoses		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		

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Burkart 2000 (*Continued*)

			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Unclear		

Callahan 2002

Study characteristics	
Patient sampling	"For the community-based sample, the geographic target area consisted of 29 contiguous census tracts with a total population of 82,387 and total households of 32,954 in the 1990 US Census. Black persons comprised 86% of this population, which also represents more than 2/3 of Indianapolis' elderly black population. A random sample of 60% of residential addresses was constructed by the IndianapolisWater Company using all residential addresses in the target area, and identified homes

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	were then visited by interviewers from May 1, 1992-April 30, 1993. Patients residing in nursing homes are not included in this sample. Eligible subjects had to be (1) a resident at a sampled address, (2) black, and (3) age 65 years or older. A total of 7590 households were approached, 4915 of which did not have an eligible resident. Of the 2582 eligible persons, 2212 (85.7%) agreed to participate. These subjects were screened with the Community Screening Instrument for Dementia (CSI-D) . . "Items for the CSI-D were selected from several widely used screening instruments including . . . the Mini-Mental State Examination."
Patient characteristics and setting	Community-based sample only 344 participants Mean age 74.4 years (range 65-99) 59.4% women 100% black 10.4 years of education 4.3% dementia 26.4% cognitively impaired Mean MMSE 26.1
Index tests	MMSE
Target condition and reference standard(s)	Dementia, DSM-III-R AND ICD-10 (Both necessary). NINCDS/ADRDA for possible or probable Alzheimer's disease
Flow and timing	"A stratified sample of the community-based subjects was selected for full clinical assessments based on their performance on the CSI-D. All subjects who scored poorly on the CSI-D were invited for clinical assessments and we also selected a 50% sample of those with intermediate performance, and a 5% sample of those with good performance. Patients aged 75 and older were over-sampled in the 5% sample so that 75% of the patients with good performance on the CSI-D would be 75 years of age or older . . "There were 351 patients selected for full clinical assessments but seven were too severely impaired to complete the standardized questionnaires. Data for the remaining 344 (98%) subjects are included here"
Comparative	
Notes	-

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

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Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Unclear		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

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Carnero-Pardo 2013

Study characteristics	
Patient sampling	Sampled from Granada and Madrid, Spain. Sampling was prospective and consecutive and included all those subjects who had memory loss complaints from the patient, the family or the person accompanying them, or that was suspected by the doctor on the basis of general observations
Patient characteristics and setting	255 (70.8%) women and 105 men, average age 72.6 years, 30 people (8.3%) were illiterate, 180 had less than primary education, 180 had more than primary education. Average MMSE score was 21.1
Index tests	MMSE The MMSE was carried out in primary care, validated in the NORMACODEM study (Blesa 2001) "doing without the spelling of world backwards" - this is one of the items in the MMSE, and an alternative question of serial subtractions of 7 from 100 may be used instead
Target condition and reference standard(s)	Dementia, DSM-IV-TR The reference standard was conducted in specialised care by an expert neurologist, without knowing the results of the MMSE
Flow and timing	All of the selected subjects independent of the results of the screening test underwent the reference standard (complete verification) In the study from Granada, as it is explained in the primary study record, the maximum time interval between assessments in the Primary Care Center and Cognitive Behavioral Neurology Unit was 2 weeks. In the study from Madrid, the interval between both evaluations was 31.05 ± 49.2 days (range 0-329) The study in Granada was conducted in 4 health centres during 1 year (1 Feb 2008 to 31 Jan 2009) ; whereas the sample from Madrid was largely (174 subjects) from 1 health centre and was selected between 1 April 2000 and 31 October 2002
Comparative	
Notes	Translated by Mr William Eustace on 31 October 2014.

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low

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Carnero-Pardo 2013 (*Continued*)

DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Correira 2001

Study characteristics	
Patient sampling	City of Recife, Brazil. The elderly were identified and invited to participate in a survey by a trained census or community health agent working in the area who scheduled an interview with the researcher
Patient characteristics and setting	Community-dwelling elderly aged 65 or more, had to have an informant who had known them for at least 10 years prior to the study

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Correira 2001 (*Continued*)

Index tests	MMSE conducted in Portuguese. The MMSE cut point scores for cognitive impairment according to education were set as follows: Illiterate = 20, 1-4 years of education = 25, 5-8 years of education = 26, 9-11 years of education = 28, and 29 for those with more than 11 years of schooling		
Target condition and reference standard(s)	Dementia. DSM-IV		
Flow and timing	The data were collected from October 2008 to January 2009		
Comparative			
Notes	The education adjusted thresholds, particularly for those with more than 11 years of schooling were very high (29 out of 30 for this group,) and we are unsure how this would be applicable		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Unclear		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Unclear		
			Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		

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Correira 2001 (*Continued*)

Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Cruz-Orduna 2012

Study characteristics	
Patient sampling	Systematically included all individuals who attended the 7 medical clinics of the Pena Prieta Primary Care Centre (Health District 1, Autonomous Community of Madrid) between 1 April 2000 and 31 October 2002.
Patient characteristics and setting	Age 50-88 inclusive Any complaint or suspicion, raised by the patient, an informant or the PCP, related to cognition, cognition-related functions (i.e. performance of activities of daily living, ADLs) or behaviour, of unknown aetiology Those with no informant were excluded 70.9% women In half of the cases (49.5%), patient and informant lived together
Index tests	MMSE (validated Spanish version)
Target condition and reference standard(s)	Dementia diagnosed according to DSM-IV-R
Flow and timing	If the patient and the informant gave their consent, the detection instruments were applied and an appointment was made to carry out a formal neuropsychological workup some days later. Patients who did not present with an informant and wished to undergo the formal neuropsychological evaluation and assessment by a neurologist were permitted to do so, although they were not included in the present study

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Comparative			
Notes	27% of the 15 people with dementia were illiterate, compared with 7% of the people with MCI and 0 of those with normal cognition. 9% of those with normal cognition had a superior education compared with 4% of those with MCI and 0 of those with dementia The mean MMSE score we quote in the covariate section is taken from the related Olazarán paper which includes those people with no informant (16 people who weren't included in the analysis): 25.1 = NCI 20.8 = MCI 16.1 = dementia		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to	Yes		

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Cruz-Orduna 2012 (*Continued*)

be repeated in an independent study?			
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Eefsting 1997

Study characteristics			
Patient sampling	Multi-stage stratified randomised sampling		
Patient characteristics and setting	Community based population		
Index tests	MMSE Dutch validated version		
Target condition and reference standard(s)	Dementia		
Flow and timing	A proportion of each scoring band was given the reference standard within 6 weeks of index test		
Comparative			
Notes	The diagnostic utility was weighted to the whole population (2151) based on 390 people who were clinically assessed		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

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Eefsting 1997 (*Continued*)

Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	No		

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Fichter 1995

Study characteristics			
Patient sampling	Random sample of 402 people were invited, of whom 358 participated		
Patient characteristics and setting	Over 85 in Munich in 1990. Sample included residents of homes for the elderly		
Index tests	MMSE included in SIDAM		
Target condition and reference standard(s)	All dementias according to DSM-III-R		
Flow and timing	Index test and reference standard were done concurrently		
Comparative			
Notes	There may be some incorporation bias due to same person doing both tests concurrently No information on diagnostic accuracy is available despite attempting to contact the authors		

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			

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Fichter 1995 (*Continued*)

Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Fillenbaum 1990

Study characteristics	
Patient sampling	Stratified from larger sample of 4164 residents. They sampled based on the SPMSQ score and assessed 164 people with MMSE, all of whom underwent a reference standard
Patient characteristics and setting	Half of the sample lives in a primarily urban county, half in rural counties. All levels of education and socioeconomic status represented. Mixed ethnicity. 54% black. > 65 years old
Index tests	MMSE administered as part of a battery of tests
Target condition and reference standard(s)	Dementia according to DSM-III
Flow and timing	We have concerns because although 164 people underwent both index test and reference standard, the diagnostic utility is presented as representative of 4164 even though the vast majority of them didn't undergo either of the tests
Comparative	
Notes	The diagnostic utility was weighted to the whole population (4164) based on 164 people who were clinically assessed. There was no raw data for the 164 people who actually received the test. Specificity was presented for black people and white people respectively as 58% and 94% and sensitivity was reported as 100% in both groups, though as stated we have concerns because the

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	figures are "weighted to represent the total five county black and white community". No raw data is available despite attempting to contact authors

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			

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Fillenbaum 1990 (*Continued*)

Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Frank 1996

Study characteristics			
Patient sampling	1692 community-dwelling people aged 55 and older from the Rancho Bernardo study		
Patient characteristics and setting	Of the sample, 380 people were in this analysis aged 65-94. 75% of men and 64% women attended college. There were 167 men and 213 women		
Index tests	MMSE		
Target condition and reference standard(s)	Alzheimer's disease diagnosed according to NINCS-ARDRA		
Flow and timing	No information given on timing. It would appear that everyone who underwent the index test also received the reference standard		
Comparative			
Notes	No information on diagnostic accuracy was available despite attempting to contact the authors		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			

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Frank 1996 (*Continued*)

If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	Yes		

Helsinki Aging Study 1994

Study characteristics	
Patient sampling	A random sample was identified from the community register which included all citizens of Helsinki: 300 75-year olds, 300 80-year olds and 300 85-year olds living in Helsinki on 1 January 1989 - a total 656 participants, which was 83% of the sample (240 aged 75, 214 aged 80 and 202 aged 85)
Patient characteristics and setting	Community sample of people > 75 in Helsinki, Finland. Urban population. Reference standard was given only to those with a CDR score of $\geq$ 0.5 (i.e. those with MCI or dementia)
Index tests	MMSE (presumably Finnish or Russian but not stated)

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Helsinki Aging Study 1994 (*Continued*)

Target condition and reference standard(s)	All dementia as diagnosed by DMS-III-R		
Flow and timing	17 subjects were unable to complete the MMSE due to severe dementia that was diagnosed at reference standard. Subjects were given a CDR as assessed by a GP. On the basis of this, screen positives (people scoring 0.5 or more) were given neurological evaluation (N = 174)		
Comparative			
Notes	Because of partial verification it is not possible to fully complete the 2 x 2 table as only information on people who had dementia is available		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			High
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Unclear		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		

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Helsinki Aging Study 1994 (*Continued*)

Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Heun 1998

Study characteristics			
Patient sampling	Subjects were a stratified sample with an over-representation of older and male subjects for invitation. Interview rate was 291 of 1193. Participants were younger, more often male and cognitively normal than invited population		
Patient characteristics and setting	Community setting. Patients aged between 60-100		
Index tests	MMSE as part of SIDAM		
Target condition and reference standard(s)	Dementia according to DSM-III-R		
Flow and timing	MMSE was conducted as part of the SIDAM and formal diagnosis was made with the information gathered concurrently at a later point		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

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Heun 1998 (*Continued*)

Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	No		

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Iavarone 2006

Study characteristics			
Patient sampling	A random sample of 300 residents out of 1089 residents > 60 years of age living in San Marcinello (Campania) received door-to-door visit by a specialised team including a geriatrician and a 5th year psychology student		
Patient characteristics and setting	Residents of a rural community in Southern Italy (San Marcinello, province of Caserta). Average age was 71.9, average 3.2 years of education, average MMSE was 19.7, 58% women		
Index tests	Validated version of the Italian MMSE, corrected for education and age		
Target condition and reference standard(s)	Dementia diagnosed according to DSM-IV. Due to the fact that the reference standard was performed at the same time as the index tests, we have some concerns that the outcome of the reference standard may have been affected by the index test scores		
Flow and timing	Index test and reference standard information was collected in the same interview for all participants. Due to this process there may be some risk of incorporation bias		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		

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Iavarone 2006 (*Continued*)

			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Jacinto 2011

Study characteristics	
Patient sampling	This study was carried out at the Albert Einstein long-term care institutions (LTCI), a Brazilian facility for elderly that includes a nursing home service, an assisted living facility, and an outpatient geriatric clinic It was a cross-sectional study with 86 elders being invited to participate; they were independent and semi-dependent residents living in the LTCI. 58 agreed to participate in the study; the remaining 28 who refused had no statistical difference in relation to gender, age and dependency level (P > 0. 05 - actual p value not given) when compared to the included ones
Patient characteristics and setting	As population ages, LTCIs play a crucial role in the elderly care. Although LTCIs are historically characterised as places where care-demanding people live, more frequently healthy elderly have decided to live in these facilities for many different reasons (more intense social contact or even enjoying what is offered at LTCIs such as balanced and proper food, recreational and physical activity and specialised medical care). The participants had 60 or more years and mean educational level of 10 years

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Index tests	MMSE (we assume a validated version of the Portuguese translation). "The Mini Mental State Examination (MMSE) has been widely studied in different populations, including in Brazil. Its performance is closely related to schooling and cutoff scores for the Brazilian population have been well established." The MMSE cut points were adjusted according to level of education (as from Bertolucci et al 1994) : 13 for illiterate, 18 for elementary and middle school educated and 26 for high school education		
Target condition and reference standard(s)	Dementia diagnosed according to DSM-IV		
Flow and timing	There is no description of the flow and timing of this paper		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
			High
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Unclear		
			Unclear
DOMAIN 3: Reference Standard			

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Jacinto 2011 (*Continued*)

Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	Unclear		

Jeong 2004

Study characteristics			
Patient sampling	Participants > 65 were recruited in Noam-dong, Namwon City, South Korea. Of 522 eligible, 235 completed tests		
Patient characteristics and setting	General community population, small South Korean city of 6883 population		
Index tests	Korean version of MMSE		
Target condition and reference standard(s)	DSM-IV		
Flow and timing	No information given on timing of reference standard. All participants received the reference standard		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**

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Jeong 2004 (*Continued*)

DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	Yes		

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Kahle-Wrobleski 2007

Study characteristics			
Patient sampling	At the beginning of 2001, 1150 of the original Southern California Leisure World 90 + study cohort were invited to join. N = 524		
Patient characteristics and setting	90+ LeisureWorld (retirement community) inhabitants		
Index tests	MMSE as part of 3MS		
Target condition and reference standard(s)	Dementia according to DSM-IV		
Flow and timing	Concurrent index test and reference standard. 86 participants failed to complete evaluation and were documented. 3 additional participants did not report their educational status and were excluded		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low

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Kahle-Wrobleski 2007 (*Continued*)

DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	No		

Kathriarachchi 2005

Study characteristics	
Patient sampling	All households with individuals > 65 were selected from a database of households maintained by Colombo District University of Sri Jayewardenepura and from that, a stratified computer-generated random sample of 400 people was selected as the study population. Of those, they evaluated only 363
Patient characteristics and setting	Semi-urban community in Sri Lanka
Index tests	MMSE Sinhalese version, previously validated by Da Silva 2002
Target condition and reference standard(s)	Dementia diagnosed according to CDR
Flow and timing	400 participants were initially identified; 363 were evaluated at phase I. The rest were difficult to assess due to unavailability of the selected individuals or their caregivers after repeated attempts to contact them. Of the 363, a sample of 40 individuals was selected for phase II. This was a concentrated sample of individuals who had scores ranging from normal to severe dementia on the rating scales (MMSE, IQCODE). Of the 40 who were selected for phase II, only 37 were evaluated. 3 were not evaluated due to death or moving. Of the 37 evaluated on phase II, 14 had dementia

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Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			

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Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Keskinoglu 2009

Study characteristics	
Patient sampling	Population of the elderly were 4012 subjects living in Narl dere, and cluster sampling method was used for sample size. Using the Epi-Info 2000 package, the minimum sample size based on sensitivity of 95%, 2% precision confidence interval (CI) of 95% was calculated as 407 elderly subjects. Given the design effect (1.2), the calculated sample size was 488 elderly. The number of houses including this sample size was requested from Turkish Statistical Institute (TUIK). TUIK reported 2601 houses, including 50 clusters of houses for sample size of district, and 517 elderly persons were determined to reside in a total of 2401 visited houses. Participation rate was 94.8% (490 elderly)
Patient characteristics and setting	This cross-sectional study was conducted among elderly individuals aged ≥ 65 in the town of Narlýdere (an urban area) in the Turkish province of Izmir. Mean age of the total 490 elderly subjects was 71.8 years (range 65-114 years; SD 6.5). Of the elderly population, 59.2% were females, 70. 8% fell in the younger age group (65-74 years) and 62.7% were married. The mean schooling year was 1.6 years (SD 0.07), 34.7% were illiterate and 50.4% did not graduate from primary school. In our study population, 9.8% of the subjects were socially uninsured, and 27.2% did not have any personal income
Index tests	rMMSE-T. Researchers exposed some problems regarding some items of the previously validated Turkish version of MMSE (MMSE-T). The index test in this study is an attempt to make a Turkish version that is more like the original Folstein MMSE
Target condition and reference standard(s)	Dementia diagnosed according to DSM-IV-R
Flow and timing	All subjects who screened positive and negative were transported to Dokuz Eylul University Hospital, Department of Neurology in same week, and clinical diagnosis of dementia were made by the senior neurologist using DSM-IV-R
Comparative	
Notes	Data on diagnostic accuracy were only available stratified by educational level, and not adjusted for education. We attempted to contact the authors to obtain non-stratified data but had no reply Because it is not clear what level of education would meet the definition of 'educated' we were unable to combine the stratified tables Total 490 participants (170 illiterate, 77 literate, 128 primary school, 29 middle school, 53 high

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	school, 3 university) For educated elderly (definition and numbers unclear, no confidence intervals) Cut points 19 indicating normal sensitivity 45.5%, specificity 97.8% 20 indicating normal sensitivity 63.6%, specificity 97.8% 21 indicating normal sensitivity 72.7%, specificity 97.0% 22 indicating normal sensitivity 81.8%, specificity 97.0% 23 indicating normal sensitivity 90.9%, specificity 97.0% 24 indicating normal sensitivity 90.9%, specificity 89.7% 25 indicating normal sensitivity 90.9%, specificity 78.4% For educated elderly (definition unclear and numbers unclear, no confidence intervals) Cut points 18 indicating normal sensitivity 76.9%, specificity 92.8% 19 indicating normal sensitivity 82.7%, specificity 92.3% 20 indicating normal sensitivity 86.5%, specificity 85.1% 21 indicating normal sensitivity 88.5%, specificity 77.9% 22 indicating normal sensitivity 92.3%, specificity 73.3% 23 indicating normal sensitivity 92.3%, specificity 65.6%

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Unclear
DOMAIN 3: Reference Standard			

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Keskinoglu 2009 (*Continued*)

Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Kungsholmen Study 1992

Study characteristics	
Patient sampling	All inhabitants > 74 years of age in an area of Stockholm (Kungsholmen) in October 1987 (2368 individuals) living at home or in institutions. 1810 participated
Patient characteristics and setting	Community setting over 74 in an area of Stockholm, Sweden. Relatively well-educated (mean 8.77 years of education)
Index tests	MMSE Swedish version
Target condition and reference standard(s)	All dementia diagnosed according to DSM-III-R
Flow and timing	The nurses saw the patients to do MMSE an average of 2 months before the clinical diagnosis. In phase 1 the MMSE was used as a screening test with 24 or above indicating normality. In phase 2 all of those scoring 23 or less (385) plus a gender- and age-matched sample (354) of the screen negatives (total 1425) were given a clinical diagnosis
Comparative	
Notes	-
Methodological quality	

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Kungsholmen Study 1992 (*Continued*)

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	No		

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Lam 2008

Study characteristics			
Patient sampling	Households were randomly selected from census records in Hong Kong. 6891 > 60 were identified and 6100 received MMSE. Nested case-control		
Patient characteristics and setting	Community-based sample of people aged > 60 in Hong Kong		
Index tests	Validated version of Chinese MMSE		
Target condition and reference standard(s)	Dementia according to DSM-IV		
Flow and timing	6891 invited, 6100 participated MMSE of those 2073 screened positive (CMMSE < 19 for illiterate participants; < 21, 1-2 years education; < 23, 2 + years education). Of those, 1336 refused to participate in reference standard and 737 went on to reference standard, of those 143 had dementia 194 of the 4027 who screened negative were clinically assessed, of whom none had dementia Not clear what the timing of the reference standard was in relation to index test		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		

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Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Lavery 2007

Study characteristics	
Patient sampling	"The Steel Valley Seniors Survey was a clinical epidemiologic study of dementia in primary care patients aged 65 years and older in a small-town community in southwestern Pennsylvania. From 1999 to 2001, participants were recruited from the offices of 15 physicians who provided care to older adults and agreed to provide access to patients and to medical records of consenting patients. Participants were designated as 'symptomatic' if self-reported memory complaints were documented in their charts. Reports by family members, if any, were excluded because many participants were unaccompanied by relatives when they visited their physicians."
Patient characteristics and setting	"Among the 642 participants selected for comprehensive assessment, those who did and did not undergo the assessment were similar (P > 0.05 - actual p value not given) with regard to age (77.5 vs 77.7 years), sex, (68.7% vs 64.0% women), education (66.8% vs 63.3% with $\geq$ 12 years), and race (92.5% vs 93.5% white). However, those assessed had a marginally higher mean (SD) MMSE

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	score than those who were not (24.5 (SD 3.4) vs 24.0 (SD 3.2), P = 0.047)."
Index tests	MMSE
Target condition and reference standard(s)	Dementia according to CDR ("A standard algorithm is used to generate a summary score ranging from 0 (no dementia) through 0.5, 1, 2, and 3, reflecting questionable, mild, moderate, and severe dementia. A CDR rating ≥1 was treated as a diagnosis of dementia."
Flow and timing	"All participants who scored ≤ 24 on the MMSE, and a randomly selected comparison group of participants who scored ≥ 25, were offered a comprehensive assessment at home. Of 1107 primary care patients aged 65 + years screened with the MMSE in the physicians' offices, the comprehensive assessment was offered to 642 participants: 343 with MMSE scores ≤ 24 and a comparison group of 299 randomly selected from those with scores ≥ 25. 3 of the 642 (0.5%) moved away, 3 (0.5%) died before the home visit, and 358 (55.8%) underwent the comprehensive assessments."
Comparative	
Notes	No information on diagnostic accuracy is available for the total sample, despite attempting to contact the authors. We have used data on the people without memory complaints

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low

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Lavery 2007 (*Continued*)

DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	No		

Lee 2002

Study characteristics	
Patient sampling	The study was conducted from June 1999 to April 2000 in Kwanak district, Seoul, South Korea. A disproportionate age-stratified random sample of 953 ≥ 65 was drawn, with a deliberate oversampling of those over 80
Patient characteristics and setting	The total population of Kwanak district was 533,577, of whom 4% of the population was ≥ 65. 67.5% of the invited population participated (N = 643). Of these, 66% were women. 32% were 65-69 (the largest age band). 43.4% had no education, 35.3% had 1-6 years of education and 21. 3% had ≥ 7 years of education. The mean MMSE score in from the participants was 21.5
Index tests	Korean MMSE (validated)
Target condition and reference standard(s)	Dementia diagnosed according to DSM-IV
Flow and timing	A stratified sample of those in phase I (index test stage) were invited to phase II (reference standard) by a neurologist. 307 were drawn from across the scores on the index test to have the reference standard
Comparative	

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Notes	No 2 x 2 data were presented. We contacted the authors for this information but received no response		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Unclear		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	No		
			Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			

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Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Li 2006

Study characteristics			
Patient sampling	Subjects were randomly selected elderly Chinese Singaporeans. Exclusions were for head trauma, stroke, evidence of cerebrovascular disease, neurological disease, systemic illness or unstable medical conditions that were judged as having a possible effect on the tested aspects. Also excluded were those using, or with a history of using benzodiazepines or barbituates		
Patient characteristics and setting	2/3 subjects were drawn from the community and 1/3 from secondary care. Subjects were 65-90 with normal hearing and vision. 50.7% female with the majority of subjects between 70-75		
Index tests	MMSE offered in both Chinese (validated) and English		
Target condition and reference standard(s)	Alzheimer's disease diagnosed according to NINCDS-ADRDA and MCI as diagnosed by CDR		
Flow and timing	The test battery was performed all at once, including the reference standard		
Comparative			
Notes	Data were presented of diagnostic accuracy for MCI and MCI and AD together, but not for AD separately. We wrote to the authors for this data but received no response		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	No		

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			High
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Unclear		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Unclear		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			High
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Lindesay 1997

Study characteristics	
Patient sampling	Random sample of age ≥ 65 registered with GP in Leicester
Patient characteristics and setting	Community-based sample of people aged > 65 in Leicester, UK

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Lindesay 1997 (*Continued*)

Index tests	MMSE
Target condition and reference standard(s)	All dementia. ICD-10
Flow and timing	The time between 1st and 2nd interviews was median 9 weeks. Full psychiatric assessment and reference standard was restricted to those who scored less than 22, or who had a CARE-D score (depression rating) of > 7 on first screen and a random third of the rest
Comparative	

Notes	2 x 2 data were only available stratified by ethnic origin. We wrote to the authors to ask for unstratified data but received no response. The data that were presented were "weighted according to the sampling fraction at second stage diagnostic interview": 74 of total 207 Gujarati people sampled (149 participating) and 59 of total 185 white people sampled (148 participating)
	Optimal cut point of MMSE to detect
	• Moderate or Severe dementia (definite)
	  ○ For Gujarati participants: cut point 18, sensitivity 67%, specificity 82%
	  ○ For white participants: cut point 18, sensitivity 100%, specificity 93%
	• Mild, Moderate or Severe dementia (definite)
	  ○ For Gujarati participants: cut point 18, sensitivity 67%, specificity 82%
	  ○ For white participants: cut point 20, sensitivity 100%, specificity 97%
	• Mild, Moderate or Severe dementia (possible or definite)
	  ○ For Gujarati participants: cut point 21, sensitivity 73%, specificity 69%
	  ○ For white participants: cut point 23, sensitivity 91%, specificity 80%

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		

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Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	No		

Liu 1996a

Study characteristics	
Patient sampling	A representative population of San-Ming district in Kaohshiung City (an industrial port in Southern Taiwan) - 20 of 86 administrative areas were chosen and then 60 participants randomly from each area. This was a sample of 1200 people [of whom 1016 were interviewed] representing 12,356 people aged ≥ 65 years
Patient characteristics and setting	535 men, 481 (47%) women, 72.3% were aged 65-74. 42.6% were illiterate. 29.4% had been to elementary school. 28% had been to high school. Overall prevalence of dementia 4.4%
Index tests	Validated version of Chinese MMSE. "Scores were below 17 in the illiterate group, below 21 in the elementary school educated group, and below 25 in the high school educated group." The review authors take the previous sentence to be the cut points for the 3 groups; however, due to ambiguity in the language this is not entirely clear

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Liu 1996a (*Continued*)

Target condition and reference standard(s)	Dementia diagnosed according to DSM-III		
Flow and timing	Of the 1200 sampled, 1016 were interviewed: 50 refused, 91 couldn't be contacted, 30 had changed address, 9 were sick and 4 were deceased All those screening positive on CMMSE went on to receive full clinical diagnosis along with a 5% sample of those screening negative If participants performed poorly on the CMMSE (lower than cut point + 2), a proxy (usually a close relative or caregiver) was interviewed for the Blessed Dementia Rating Scale and questionnaires		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Unclear		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		

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Liu 1996a (*Continued*)

Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Lourenco 2006

Study characteristics			
Patient sampling	A convenience sample of those over 65 who presented at outpatient primary care clinic. We have confirmed that this meets the definition of primary care in the protocol		
Patient characteristics and setting	Primary care patients aged ≥ 65, poorly educated [only 4.3% had more than 8 years of schooling]. Low socioeconomic status. 26.4% illiterate		
Index tests	MMSE, validated and modified Portuguese version		
Target condition and reference standard(s)	All dementia. Diagnosed according to DSM-IV and ICD-10		
Flow and timing	A research assistant trained in conducting MMSE gave index test. The geriatricians and neuropsychologists made a formal diagnosis according to ICD-10 and DSM-IV		
Comparative			
Notes	20 (6.6%) of participants had suffered a stroke and 57 (18.8%) had depression		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

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Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

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Macedo Montano 2005

Study characteristics			
Patient sampling	Participant survivors of a cohort who were ≥ 65 years and residing in Sao Paolo, Brazil when recruited 7 years previously		
Patient characteristics and setting	Community setting, > 72 years old in Sao Paolo, Brazil		
Index tests	MMSE, presumably translated into Portuguese (not stated)		
Target condition and reference standard(s)	Dementia according to DSM-IV and NINCDS-ADRDA		
Flow and timing	Timing unclear. All elderly scoring < 26 received reference standard along with a sample of the rest		
Comparative			
Notes	The quality of reporting in this paper made it difficult to make judgement on the risk of bias. We have concerns about the quality of conduct		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Unclear		
			Unclear

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Macedo Montano 2005 (*Continued*)

DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Mackinnon 2003

Study characteristics	
Patient sampling	Probability sample of persons aged ≥ 70 years drawn from the electoral roll for Canberra and the neighbouring town of Queanbeyan and stratified to recruit equal numbers of male and female
Patient characteristics and setting	Asymptomatic community ≥ 70 in Australia
Index tests	MMSE
Target condition and reference standard(s)	Dementia diagnosed according to DSM-III-R
Flow and timing	Participants were interviewed in their homes by lay interviewers. MMSE was administered as part of the interview. Diagnosis according to DSM-III-R was made using information from interviews after completion of all interviews
Comparative	

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Notes	Of 945 participants, interviews including the IQCODE could be obtained for 694 participants. The MMSE scores were not available for 48 participants. Diagnoses of dementia could not be made for 19 persons. The analyses presented here were undertaken on 646 participants for whom all data was available

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			

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Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Maki 2000

Study characteristics			
Patient sampling	1438 participants were invited (the entire > 65 population of the town), of whom 1255 agreed to take part. Those who lived alone were excluded due to lack of informant, leaving 818. The data were presented for 662 subjects		
Patient characteristics and setting	Elderly general population > 65 in in rural community of Nakayama town in Ehime, Japan		
Index tests	MMSE (we presume a Japanese version - not reported)		
Target condition and reference standard(s)	All dementia diagnosed according to DSM-III-R		
Flow and timing	The paper says that "we analysed data from 818 subjects for this paper" but in fact, data is only presented for 662 people, and no reason is given for this discrepancy. 258 subjects were selected for the clinical evaluation using at least 1 of the following criteria 1) MMSE score of ≤ 23, 2) SMQ (validated short memory questionnaire) score of ≤ 39/46, 3) Karasawa scale score of ≥ 1 and, 4) 0 score on 3-word recall. Additionally, they reselected 50 of the remaining 560 at random to undergo reference standard. This totals 308. We cannot see where the total of 662 has come from. Timing of tests is not clear		
Comparative			
Notes	-		

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

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Did the study avoid inappropriate exclusions?	No		
			High
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Unclear		
			Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

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Mingyuan 1998

Study characteristics			
Patient sampling	The study population was based on a study conducted in 1987. In 1987, a total of 5055 people were included and according to the DSM-III-R , 159 of the 5055 had dementia, 4896 of the 5055 were normal In 1992, the 4896 people were investigated again, and 792 died, 1080 were lost to follow-up, so 3024 people were involved in the present study		
Patient characteristics and setting	57.34% female		
Index tests	MMSE (we presume CMMSE, but no information about validation is given)		
Target condition and reference standard(s)	Dementia according to DSM-III-R		
Flow and timing	Reference standard was given to 711 participants whose MMSE were positive (the total score was lower than the cut point which was based on the education level) and 321 participants whose MMSE were negative (stratified sampling)		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Unclear		
Were sufficient data on MMSE application given for the test to be repeated in an independent	No		

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Mingyuan 1998 (*Continued*)

study?			
			Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Unclear
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

MoVies Study 1993

Study characteristics	
Patient sampling	The validation sample for this study was an age-stratified random sample drawn from a population of more than 17,000 older adults in 23 communities of the mid-Monongahela Valley of Southwestern Pennsylvania (the MoVIES sample, initiated in the early 1990s)
Patient characteristics and setting	Participants were English speakers aged $\geq$ 65 (mean age 73.1), with at least 6 years of formal education (median education was high school graduate), living in the community (southwestern Pennsylvania). 96.6% white, 54.6% female, 56.9% married and 31.1% living alone
Index tests	Standard MMSE
Target condition and reference standard(s)	Dementia diagnosed according to DSM-III-R. There is concern about the conduct of the reference standard. There were 2 stages, in the first instance, trained non-specialists gathered information and a psychiatrist made a tentative diagnosis. Those who were identified as not demented in this initial diagnosis were not evaluated further. People who were identified as possibly or probably demented were evaluated by a specialist. Some cases of dementia may not have been identified

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MoVies Study 1993 (*Continued*)

Flow and timing	It is unclear how many of the entire group received the reference standard. The reference standard comprised 2 stages: in the first instance, trained non-specialists gathered information and a psychiatrist made a tentative diagnosis. Those who were identified as not demented in this initial diagnosis were not evaluated further. People who were identified as possibly or probably demented were evaluated by a specialist. Some cases of dementia may not have been identified. From the way that the data is presented, we can work out patient flow through index test and reference standard. However, we are confident that all test positives and some test negatives received the reference standard
Comparative	
Notes	Data presented are drawn from multiple papers relating to the MoVies study, largely Borson 2003 and Ganguli 1993. We have contacted the authors to try to reconcile some differences in data presented, particularly regarding sample size and flow of participants, but unfortunately, they were unable to clarify

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		

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MoVies Study 1993 (*Continued*)

Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Pandav 2002

Study characteristics			
Patient sampling	Population-based, largely illiterate sample of 5126 individuals aged ≥ 55 in 28 villages in the rural community of Ballabgarh in northern India out of a total population of 5134		
Patient characteristics and setting	Population-based, largely illiterate (73.3%) sample of 5126 individuals aged ≥ 55 in 28 villages in the rural community of Ballabgarh in northern India. 95.4% of women were illiterate, as were 53.8% of men. Illiteracy was defined by inability to read a local newspaper and write a sentence		
Index tests	HMSE (Hindi Mental State Examination) being validated in this study		
Target condition and reference standard(s)	Dementia diagnosed according to DSM-III-R		
Flow and timing	Of the 5126 subjects who were thus cognitively or functionally screened, 536 (10.5%) were selected as screen-positives for standardised clinical diagnosis and a random sample of 270 (5.3%) were selected as screen negatives to also undergo standardised clinical diagnostic evaluation		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

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Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Unclear		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

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PAQUID Study

Study characteristics			
Patient sampling	A random sample of 4050 was drawn according to a 3-stage sampling design. The first 2 stages resulted in the selection of 37 parishes distributed across Gironde, France. Subjects were then randomly selected from the electoral lists after stratification by age and sex		
Patient characteristics and setting	2792 subjects 65 years and older living independently in Gironde, France. The age and sex distribution for the sample was similar to the overall target population. 22.2% of men (619) were aged 65-74, 14.9% of men (417) were aged 75-84, 3% (84) were over 84 (total 1120 men). 28.1% (784) were aged 65-74, 23.9% (667) were aged 75-84, 7.9% (221) were aged > 84 (total 1672 women)		
Index tests	We assume that the MMSE was conducted in French. There was no data given as to a validated translation		
Target condition and reference standard(s)	Dementia diagnosed according to DSM-III		
Flow and timing	All 2792 subjects were administered psychometric tests (including MMSE) at home by a psychologist and applied the DSM-III diagnostic criteria		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent	Unclear		

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PAQUID Study (*Continued*)

study?			
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Phantumchinda 1991

Study characteristics	
Patient sampling	A random sample of 500 people > 60, resident in a large urban slum, Klong Toey, Bangkok. Had to have lived in the slum for over a year and willing to take part. Interviewed the elderly subjects and their close relatives. Started in 1989
Patient characteristics and setting	Low socioeconomic status. 41% are aged 60-64; 26% are aged 65-69; 17% aged 70-74. Only 6. 2% were > 80. Low education: 87.4% had < 4 years of education
Index tests	Field survey version of the MMSE, translated into Thai (non-validated version)
Target condition and reference standard(s)	Dementia according to DSM-III-R
Flow and timing	Everyone was seen by a physician. Those thought to have dementia were then seen by a neurologist for confirmation. More confident in the determination of true positives. 500 out of 588 agreed to take part

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Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Unclear		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			

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Phantumchinda 1991 (*Continued*)

Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	Yes		

Pond 1994

Study characteristics	
Patient sampling	"All GPs conducting clinics at a large retirement village complex in Sydney, Australia, were approached to take part in this study, provided that they had at least 10 patients aged 70 or over who were living either independently or in hostel accommodation . . "During the pre- and post-intervention sampling phases each GP completed a 1 page questionnaire for each patient attending and recorded his/her opinion on the dementia status of each of these patients, as well as an opinion on whether the patient was depressed or not. The reasons for attendance were recorded as were major chronic illnesses . . "Of the 258 patients approached in the pre-intervention sample, 45 refused and 13 were excluded due to illness (12 physical illness; 1 probable depression), while 200 had a home interview, of which 105 had the additional CIE assessment. In the post-intervention sample, 218 patients were approached. Of these, 50 refused, 1 was excluded due to physical illness, and 167 had a home interview, including 69 who completed the CIE."
Patient characteristics and setting	Pre-intervention (academic training) Age 82.5 years (SD 5.9) Mean MMSE 26 (SD 3.7) 86% female 66% Hostel Post-intervention Age 82.9 years (SD 6.1) MMSE 25.9 (SD 3.6) 88% female 73% Hostel Hostels are "low level residential care"
Index tests	MMSE administered in the patient's own home by a trained nurse
Target condition and reference standard(s)	Dementia, DSM-III-R and ICD-10 'probable dementia' diagnoses
Flow and timing	"Patients who agreed to join the study were then, within a week of their consultation, interviewed in their own home by a registered nurse . . . A 1 in 2 subsample received an abridged version of the Canberra Interview for the Elderly (CIE),19 a structured interview with an informant component. The CIE enables the generation of a set of diagnoses for each patient based upon the DSM-III-R classification system and the draft International Classification of Diseases, version 10 (ICD-10).

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	Selection for the CIE subsample was random, taking every second consecutive case."
Comparative	
Notes	-

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	No		
			Low

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DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	No		

Ramlall 2013

Study characteristics			
Patient sampling	A convenience sample of 302 residents in a non-governmental home for the elderly housing in Durban, South Africa. A total of 1371 residents and those receiving frail care in assisted and independent living for people aged ≥ 60 years		
Patient characteristics and setting	Inclusion criteria were residents who were aged ≥ 60 years, had a minimum of 8 years of formal schooling, were able to speak, read and write in English and gave written informed consent. Exclusion criteria were residents with severe physical, mental or sensory handicap that precluded their engagement with the assessment Given these inclusion (informed written consent) and exclusion criteria, we have concerns that those most severely affected by dementia will be excluded from the study. We anticipate that this would result in an underestimation of the diagnostic utility of the test		
Index tests	MMSE		
Target condition and reference standard(s)	Dementia diagnosed according DSM-IV-R		
Flow and timing	302 were convenience sampled. Of those, 38 screen positives and 102 randomly selected screen negatives had a clinical diagnostic evaluation		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		

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Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	No		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

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Rosselli 2000

Study characteristics	
Patient sampling	The sample was obtained from the 5 principal urban conglomerates of Colombia (Bogota, Medellin, Cali, Barranquilla, Bucaramanga) according to the 1993 census. In each of these regions, sampling was carried out as follows 1. A random neighbourhood was selected with the numbers generated by a computer. 2. A second neighbourhood, again done randomly, obtained a small local area 2 hours or less from each of the 5 mentioned cities. 3. A third sample of the rural population was chosen randomly in another similar municipal. The sample was representative of Colombia as a whole.
Patient characteristics and setting	Visited 2560 homes and interviewed 9328 participants, of those, 1949 were > 50 years old. 1686 individuals responded to MMSE, but 75 were excluded because they died or only partially completed 3 or more questions. In total 1611 were included 613 were male = 38.1% 998 were women = 61.9% Average 3 years education Mean age = 62.9 years Given that the review is looking at the utility of the test in adults over the age of 65, we have marked the applicability of the population as 'of high concern'
Index tests	Translated version of the MMSE. The cut points were adjusted for education as follows: ≤ 21 for < 6 years schooling; < 24 for 7-12 years of schooling; < 27 for those with > 12 years of schooling For individuals older than 65 years of age an additional point was added to the total mark For those older than 75, 2 additional points were added to the total mark Participants with visual limitation also received 2 additional points
Target condition and reference standard(s)	Dementia, DSM-IV
Flow and timing	People who scored below a cut point were evaluated by a clinician, together with a 5% random sample of 'healthy' participants Of the 1611 participants, 536 who scored below education adjusted cut point (33.3%), 209 of these individuals suspected of possible dementia did not attend, so 327 completed evaluation. The average MMSE score of people who did not attend (19.05 ± 3.72) was statistically higher than the MMSE score of people who did attend (16.38 ± 4.54) P < 0.001. Of the 327 who completed the reference standard, 12 had dementia Of the 1075 participants with satisfactory scores on MMSE, 366 (34%) were seen by a neurologist for other reasons, and 1 of these was found to have dementia
Comparative	
Notes	Translated by Mr William Eustace on 30 October 2014

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

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Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			High
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Unclear		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Unclear		
			Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

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Rummans 1996

Study characteristics			
Patient sampling	A population-based, age-stratified, random sample of residents of Rochester, Minnesota, USA aged ≥ 65		
Patient characteristics and setting	406 people were sampled and contacted, of whom 201 agreed to participate. 65% were female. The mean age was 78.3 for men and 80.2 for women		
Index tests	MMSE with standard cut-off of 24 indicating normality, combined with AVLT		
Target condition and reference standard(s)	Dementia diagnosed according to DSM-III-R		
Flow and timing	Patients scoring 23 or below on MMSE or failing the other screens (22 in total) went on to receive reference standard, along with 15 who passed all screens		
Comparative			
Notes	Sensitivity and specificity is presented for MMSE and AVLT combined (92.3% and 100% respectively) in the paper. We contacted the authors for the separate data for MMSE only and received no response		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		

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Rummans 1996 (*Continued*)

			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Scazufca 2009

Study characteristics	
Patient sampling	Participants were those enrolled in the baseline assessment of the Sao Paulo Ageing and Health Study (SPAH). The investigation was carried out in the borough of Butantã, located on the west side of the city. Between May 2003 and April 2005 all residents aged ≥ 65 years living in 66 census sectors of the Butantã borough, covering a population of approximately 63,000 residents, were invited to participate in the SPAH. A total of 2072 persons (91.4% of those invited) were recruited through systematic door knocking. Interviews for the assessment of dementia took place at participants' residences approximately 1 week after recruitment
Patient characteristics and setting	Population based. 60.6% female, 43% aged 65-69, 27% aged 70-74, 38.5% had 0 years of education. 50% had a personal income of < USD 127 per month
Index tests	Validated version of the Brazilian version of the MMSE
Target condition and reference standard(s)	Dementia according to DSM-IV

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Scazufca 2009 (*Continued*)

Flow and timing	A total of 2072 persons were recruited. Included in the analysis were 1933 participants (93.3% of those assessed for the prevalence study). Among the 139 participants excluded, 48 were unable to answer ≥ 5 items of the questionnaire due to severe physical or mental impairment (18 cases of dementia, 20 subjects with sensory impairments - eye or hearing problems, 10 with other physical incapacities), 10 were approached but refused to answer the MMSE questions, and 81 were not approached by the research team for the battery of assessments that included the MMSE
Comparative	
Notes	Reference standard was DSM-IV applied by algorithm rather than by a psychiatrist or neurologist. Data is only presented for the diagnostic accuracy of the MMSE stratified by educational level (none, 744 participants; ≥ 1 year, 1189 participants). There were 84 people with dementia out of a total of 1933. Because we do not know the number of people with dementia in these 2 groups, despite attempting to contact the authors, it is not possible to enter the data separately and so the study cannot be included in the meta analysis No education cut points 14 indicating normal sensitivity 72.3% specificity 84.9% 15 indicating normal sensitivity 78.7% specificity 77.8% 16 indicating normal sensitivity 87.2% specificity 70.4% 17 indicating normal sensitivity 93.6% specificity 61.3% 18 indicating normal sensitivity 93.6% specificity 49.1% 19 indicating normal sensitivity 95.7% specificity 40.2% 20 indicating normal sensitivity 97.9% specificity 29.7% ≥ 1 year(s) of education cut points 18 indicating normal sensitivity 91.9%, specificity 89.5% 19 indicating normal sensitivity 91.9%, specificity 85.4% 20 indicating normal sensitivity 94.6%, specificity 78.8% 21 indicating normal sensitivity 94.6%, specificity 69.9% 22 indicating normal sensitivity 94.6%, specificity 59.9% 23 indicating normal sensitivity 94.6%, specificity 50.6% 24 indicating normal sensitivity 100%, specificity 37.6% 25 indicating normal sensitivity 100%, specificity 27.8%

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	No		

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Scazufca 2009 (*Continued*)

			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	No		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Were all patients included in the analysis?	No		

Schultz-Larsen 2007

Study characteristics	
Patient sampling	The study sample was drawn from respondents to the so-called Brønshøj-Husum Study, a 3-stage population study of dementia and functional ability among all community-dwelling elderly women (1147) and men (635) born between 1913 and 1918 and living in a district of Copenhagen in January 1994

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Schultz-Larsen 2007 (*Continued*)

Patient characteristics and setting	65% had ≤ 7 years education, 64% were women in phase 1 sample and 53.5% women at stage 2. Average age was 79 in whole sample and 80.2 in the phase 2 sample. 56% lived alone
Index tests	Standardised Danish version of the original MMSE
Target condition and reference standard(s)	Dementia according to DSM-IV
Flow and timing	In the first stage of the study, 67% (759 women and 430 men) of the population underwent a baseline and cognitive assessment in their homes by a trained research nurse using standard instruments including the MMSE. In the second stage, a subsample of initial respondents was asked to undergo a clinical neuropsychological examination. The subsample included all subjects who screened positive (MMSE < 26 among subjects with 7 years of schooling, < 27 for subjects with longer education) at the baseline assessment (N = 156) besides a random sample of individuals stratified by age and sex (N = 164) among subjects who screened negative at the baseline assessment
Comparative	
Notes	-

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		

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Schultz-Larsen 2007 (*Continued*)

			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Tang 1999

Study characteristics	
Patient sampling	Participants were cluster sampled by draw from different districts of Chengdu, China
Patient characteristics and setting	Participants were 55.79% female and had a mean age of 67.12. 53.96% (648) of the participants were from downtown; 26.56% (319) were from rural-urban continuum; 19.48% (234) were from rural settings. The education level of the participants who lived downtown were the highest, followed by the participants who lived in the rural areas. The participants living in the rural-urban continuum had the lowest educational levels
Index tests	Chinese version of MMSE but no validation information given
Target condition and reference standard(s)	Dementia diagnosed according to DSM-III-R
Flow and timing	Not all participants received the reference standard. 1. Those whose score of the CMMSE below the criteria (illiterate group: CMMSE ≤17, primary school group: CMMSE ≤20, middle school and above CMMSE ≤24) had the reference standard

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	2. Those whose score of the CMMSE was normal, but the doctor or family member suspected dementia had the reference standard 3. To avoid the missed diagnoses, 20% of the participants in the illiterate group whose CMMSE score were 18 or 19 were randomly selected to have the reference standard 4. 4% of the participants whose CMMSE score were normal were also randomly selected to have the reference standard
Comparative	
Notes	-

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Unclear		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	No		
			Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent	Yes		

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study?			
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

West Beijing Study 1989

Study characteristics			
Patient sampling	All the households with residents aged ≥ 60 years in the West district of Beijing, specifically 4 communities in the west district of Beijing		
Patient characteristics and setting	585 females, 505 males. 33.7% illiterate. Illiteracy in women 53.8%. 60.8% of those who had been employed were workers in service industry. 36.2% were professional or administrative workers. 51.2% of women and 17.1% of men were widowed. 70% lived with their children		
Index tests	The MMSE was translated into Chinese from English, with each item being discussed with a neuroepidemiologist from the United States, the late Professor B. Schoenberg		
Target condition and reference standard(s)	Dementia according to DSM-III (slightly modified). Criterion A was thus extended to be "loss of intellectual ability of sufficient severity to interfere with daily living, social and occupational functioning of a sufficient degree that help is needed on a day-to-day basis either part or all of the time"		
Flow and timing	N = 1090. Only 1072 received MMSE, of those, all those who scored ≤ 17 on MMSE (n = 42) plus a randomised sample of 5.5% (57 participants) of the rest received the full clinical examination. The 18 people who couldn't undergo an MMSE were screened using a different test, the Crichton Scale		
Comparative			
Notes	The overall prevalence of dementia was calculated as 1.3%		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

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Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Unclear
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	Yes		
			Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Unclear
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

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Wilder 1995

Study characteristics			
Patient sampling	Patients were recruited from the North Manhattan Aging Project by census		
Patient characteristics and setting	Urban setting, Manhattan, USA. 790 people in total. 355 Latino, 299 African American and 136 white. 39% were aged 78-84, 46% had 5-11 years of education		
Index tests	MMSE with some translations in real-time for non-native speakers of English		
Target condition and reference standard(s)	Dementia diagnosed according to DSM-III-R		
Flow and timing	No information about timing given. All screen positives and a portion of screen negatives were referred for reference standard		
Comparative			
Notes	We contacted the authors for 2 x 2 data and received no reply so are unable to include this study in the meta-analysis		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
			Low
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	No		
			Low

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Wilder 1995 (*Continued*)

DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

Winblad 2010

Study characteristics	
Patient sampling	A total population based clinico-epidemiological study was carried out covering all of the 1680 inhabitants aged ≥ 60 in the rural municipality of Haapajarvi in Northern Finland. Registers of health and social welfare and population interviews were used
Patient characteristics and setting	Aged ≥ 60 in the rural municipality of Haapajarvi in Northern Finland. We have concerns about the applicability due to the exclusion of previously diagnosed dementia patients
Index tests	MMSE assumed to be in Finnish. No information about validation of the translation. There is no reference at all to the index test, including the original Folstein paper
Target condition and reference standard(s)	All-cause dementia diagnosed according to DSM-IV
Flow and timing	The total ≥ 60 population was 1680, they did a first stage dementia awareness campaign. They took a random sample of 840, excluding those who they had seen at the campaign, which left 757, of whom 490 proceeded to index test Of the 490 who received the index test, they performed reference standard on 114 people. The reference standard was performed on 82 out of 110 (75%) of those who scored < 25 on MMSE. The reference standard was performed on 32 out of 380 (8.4%) of those who scored 25 or more on

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	MMSE		
Comparative			
Notes	-		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	No		
			High
DOMAIN 2: Index Test All tests			
If a threshold was used, was it pre-specified?	Yes		
Were sufficient data on MMSE application given for the test to be repeated in an independent study?	No		
			Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?	Yes		
			Low

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DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Were all patients included in the analysis?	No		

3MS: Modified Mini-Mental State Examination; **AD**: Alzheimer's disease; **ADL**: activities of daily living; **ADRDA**: Alzheimer's Disease and Related Disorders Association; **AMT**: Abbreviated Mental Test; **AVLT**: Auditory Verbal Learning Test; **CDR**: clinical dementia rating; **CIE**: Canberra Interview for the Elderly; **CMMSE**: Chinese Mini-Mental State Examination; **CSI-D**: Community Screening Instrument for Dementia; **DSM**: Diagnostic and Statistical Manual of Mental Disorders; **GPCOG**: General Practitioner Assessment of Cognition; **ICD**: International Classification of Diseases; **IQCODE**: Informant Questionnaire on Cognitive Decline in the Elderly; **LTCI**: long-term care institution; **MCI**: mild cognitive impairment; **MMSE**: Mini-Mental State Examination; **NCI**: no cognitive impairment; **NINCDS**: National Institute of Neurological and Communicative Disorders and Stroke; **PCP**: primary care practitioner; **SIDAM**: Structured Interview for Diagnosis of Dementia of the Alzheimer Type; SMQ: short memory questionnaire; **SPMSQ**: Short Portable Mental Status Questionnaire.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Al-rajeh 1999	Wrong setting (secondary care)
Almeida 1998	Wrong setting (secondary care)
Basic 2009	Wrong setting (secondary care)
Bastide 2012	Wrong setting (secondary care)
Belmin 2007	Wrong setting (secondary care)
Bermejo 1999	Wrong setting (secondary care)
Bermejo-Pareja 2009	Wrong index test (37-item MMSE)
Bland 2001	Wrong index test (3MS, not MMSE)
Borson 1999	Wrong study design (case-control)

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(*Continued*)

Borson 2000	Wrong study design (case-control)
Borson 2005	Wrong study design (case-control)
Braekhus 1995	Wrong study design (case-control; all participants pre-diagnosed as non-dementia patients)
Brooke 1999	Wrong setting (secondary care)
Burnham 2012	Wrong setting (secondary care)
Cacho 2010	Wrong setting (secondary care)
Canadian Study of Health and Aging	Wrong index test (3MS)
Cao 2012	Wrong setting (secondary care)
Carpenter 2011	Wrong setting (secondary care)
Cercy 2012	Wrong study design (case-control)
Cerveira 2009	Wrong setting (secondary care)
Cervilla 2004	Wrong study design (only those scoring 25 or less received reference standard - partial verification)
Chaves 2007	Wrong setting (secondary care)
Chaves 2009	Wrong reference standard (none; prevalence study only)
Chester 2011	Wrong reference standard (none)
Chong 2010	Wrong study design (case-control)
Clark 1999	Wrong study design (case-control; all patients had pre-diagnosed cognitive impairment)
Clarke 1991	Wrong reference standard (CAMDEX with no reference to DSM)
Cossa 1997	Wrong study design (only index test positives received the reference standard)
Cossa 1999	Wrong study design (partial verification - reference standard applied only to those with positive index test result)
Costa 2012	Wrong study design (not diagnostic test accuracy study)
Cullen 2005	Wrong reference standard

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(*Continued*)

Dahl 2007	Wrong study design (partial verification - only index test positives received reference standard)
Damian 2011	Wrong setting (secondary care)
Dash 2006	Wrong setting (secondary care)
Davous 1988	Wrong reference standard (None)
De Beaman	Wrong setting (secondary care)
De Jager 2009	Wrong study design
De Silva 2002	Wrong reference standard (CAMCOG)
Del-Ser 1997	Wrong setting (secondary care)
Derrer 2001	Wrong study design (case-control)
Dierckx 2011	Wrong study design
Diniz 2007	Wrong setting (secondary care)
Dong 2012	Wrong setting (secondary care)
Donnelly 2008	Wrong reference standard
Drachmann 1996	Wrong study design (case-control; drawn from partially secondary care population)
Duron	Wrong target condition (dementia not key outcome)
Fabrigoule 1995	Wrong study design
Feher 1992	Wrong setting (secondary care)
Fernandez-Martinez 2008	Wrong study design (partial verification - only index test positives received reference standard)
Fernandez-Martinez 2010	Wrong setting (secondary care)
Ferrero-Arias 2001	Wrong setting (secondary care)
Ferruci 1998	Wrong setting (secondary care)
Fong 2010	Wrong setting (secondary care)
Forlani	Wrong index test (not looking at accuracy of MMSE)

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(*Continued*)

Fountoulakis 1998	Wrong study design (case-control)
Fountoulakis 2000	Wrong study design (case-control)
Fratiglioni 1993	Wrong index test (not looking at accuracy of MMSE)
Fratiglioni 1994	Wrong index test (not looking at accuracy of MMSE)
Fujiawara 2003	Wrong study design (case-control; all patients had cognitive decline)
Gabryelewicz 2002	Wrong study design (partial verification - only index test positives received reference standard)
Galvin 2010	Wrong setting (prevalence of dementia over 60%. Secondary or tertiary care setting.)
Ganguli 2004b	Wrong study design (partial verification - only index test positives received reference standard)
Ganguli 2010a	Wrong study design (partial verification - only index test positives received reference standard)
Ganguli 2010b	Wrong study design (partial verification - only index test positives received reference standard)
Ganzer 2003	Wrong setting (secondary care)
Garcia	Wrong study design (case-control; all healthy participants at baseline)
Garcia 1993	Wrong reference standard (MMSE is the reference standard)
Geerlings 1999	Wrong study design (no DTA data)
Gibbons	Wrong setting (secondary care)
Goldman 2001	Wrong index test (no MMSE in study)
Gondo 2006	Wrong reference standard (none)
Grigoletto 1999	Wrong study design (case-control; excluded those with symptoms)
Grober 2008	Wrong study design (case-control; excluded those with MMSE score < 18)
Harder 1995	Wrong study design (case-control)
Hartmann 2002	Wrong setting (secondary care)
Hashizume 2004	Wrong setting (secondary care)
Helkala 2002	Wrong study design (partial verification - only those scoring < 24 on MMSE received reference standard)

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(*Continued*)

Hensel 2009	Wrong study design (case-control; excludes participants with dementia symptoms)
Hogervorst	Wrong study design
Holsinger 2012	Wrong index test (3MS data presented - no MMSE extracted)
Huppert 2005	Wrong study design (no test accuracy data)
Ibrahim 2009	Wrong study design
Ideno 2012	Wrong study design
Ihl 2005	Wrong study design (case-control)
Jagger 1992	Wrong reference standard
Jeong 2007	Wrong study design (case-control; excludes cognitively impaired)
Jervis 2007	Wrong study design (not a test accuracy study)
Jeste 1992	Wrong study design (case-control)
Jones 2010	Wrong setting (secondary care)
Jonsson 2010	Wrong study design (not a test accuracy study)
Jorm 1996	Wrong reference standard
Jorm 1997	Wrong study design (not a test accuracy study)
Kal'bus	Wrong study design (participant ages 35-65)
Kamenski 2009	Wrong reference standard (none)
Kanegae 2008	Wrong setting (secondary care)
Kaufer 2008	Wrong setting (secondary care)
Khachaturian 2000	Wrong index test (3MS)
Kirby 2001	Wrong reference standard (AGECAT with no reference to DSM)
Kliegel 2004	Wrong reference standard (none)
Kochhann 2010	Wrong study design

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(*Continued*)

Koski 2011	Wrong setting (secondary care)
Koson	Wrong study design (patients scoring < 24 on MMSE excluded)
Krigbaum 2012	Wrong study design (case-control)
Kukull 1994	Wrong study design (case-control; only dementia patients)
Kuslansky 2004	Wrong study design (case-control)
Lam	Wrong study design (looking at change in MCI)
Lam 2005a	Wrong reference standard (only CDR 0.5)
Lam 2005b	Wrong study design (no DTA data)
Larner 2012	Wrong setting (secondary care)
Larson 1984	Wrong setting (secondary care)
Lautenschlager 1986	Wrong setting (secondary care)
Law 1995	Wrong index test (3MS)
Lee	Wrong study design (prevalence of cognitive impairment)
Lee 1997	Wrong study design (partial verification; only index test positives received reference standard)
Lee 2009	Wrong study design (partial verification; only index test positives received reference standard)
Leoutsakos 2012	Wrong study design (case-control; all participants had AD)
Li 2009	Wrong study design (partial verification; only index test positives received reference standard)
Li 2013	Wrong setting (secondary care)
Limpawattana 2012	Wrong setting (secondary care)
Lin 1998	Wrong study design (partial verification; only index test positives received reference standard)
Liu 1994	Wrong index test (CASI)
Liu 1995	Wrong study design (partial verification; only index test positives received reference standard)
Liu 1996b	Wrong study design

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(*Continued*)

Liu 1998	Wrong study design (partial verification; only index test positives received reference standard)
Llibre 2009	Wrong study design (prevalence study)
Lobo 2008	Wrong study design
Lopes 2010	Wrong study design (case-control; only those with cognitive impairment)
Lopez-Pousa 1995	Wrong reference standard
Luis 2009	Wrong study design
MacKenzie 1996	Wrong study design
MacKnight 1999	Wrong index test (3MS)
MacNeill 2000	Wrong setting (secondary care)
Marcos de Vega	Wrong target condition (MCI)
Medina	Wrong study design (not DTA; no MMSE accuracy data)
Meguro 2007	Wrong study design (case-control; wrong patient population)
Molloy 1997	Wrong study design (not a DTA study)
Moretti	Wrong target condition (MCI)
Mungas 1996	Wrong study design
Murden 1991	Wrong study design
Murden 1997	Wrong study design (case-control; wrong participant population)
Nadler 1995	Wrong setting (secondary care)
Narasimhalu 2008	Wrong setting (secondary care)
Neri 2001	Wrong study design (partial verification; only index test positives received the reference standard)
Ng 2007	Wrong reference standard
Nishiwaki 2004	Wrong reference standard
Noale 2006	Wrong study design (delayed verification)

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(*Continued*)

Nourhashemi 2008	Wrong study design (case-control; wrong population)
O'Bryant 2008	Wrong study design
O'Connor 1989	Wrong study design
Olazaran 2004	Wrong target condition (MCI)
Onishi 2006	Wrong setting (secondary care)
Ostrosky-Solis 1999	Wrong study design (case-control)
Pachet 2010	Wrong study design
Pardo 1990	Wrong study design (case-control)
Perneczky 2006	Wrong setting (secondary care)
Pezzotti 2008	Wrong study design (case-control; participants with cognitive impairment only)
Pouretemad 2009	Wrong study design
Qu 2005	Wrong study design (partial verification. Only index test positives received reference standard.)
Quiroga 2004	Wrong study design (case-control)
Rabins	Wrong study design
Rai 1998	Wrong setting (secondary care)
Rai 2008	Wrong setting (secondary care)
Raina 2013	Wrong study design (case-control)
Rait 2000	Wrong reference standard
Raskind 1999	Wrong study design (No MMSE test accuracy data)
Riedel-Heller 1999	Wrong study design (case-control; only healthy participants)
Roelands 1992	Wrong study design (only index test positives received the reference standard)
Schrijnemaekers 2006	Wrong study design (case-control)
Sikkes 2013	Wrong study design (case-control)

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(*Continued*)

Spering 2012	Wrong study design
Stewart 2002	Wrong study design (normative study)
Stoppe	Wrong study design
Storey 2002	Wrong setting (tertiary care)
Storey 2004	Wrong study design
Subra 2012	Wrong target condition
Sugishita	Wrong index test (short MMSE)
Tae 2010	Wrong study design
Taillandier 2002	Wrong setting (secondary care)
Tamura	Wrong study design
Tang-Wai 2003	Wrong setting (secondary care)
Tappen 2012	Wrong setting (mixed recruitment, largely from secondary care)
Tariq 2006	Wrong setting (secondary care)
Tariska 2003	Wrong setting (secondary care)
Thibodeau 2011	Wrong study design (longitudinal change)
Thiele	Wrong study design (case-control; all subjects had MCI at baseline)
Tian	Wrong index test
Tierney 2000	Wrong setting (secondary care)
Timpano 2013	Wrong setting (secondary care; and case-control)
Tombaugh 1996	Wrong index test (3MS)
Tombaugh 2005	Wrong study design (case-control; all participants had MCI at baseline)
Travers 2013	Wrong setting (secondary care)
Trenkle 2007	Wrong target condition (MCI)

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(*Continued*)

Tschanz 2004	Wrong study design
Tuokko 1995	Wrong index test (3MS)
Uhlmann 1991	Wrong study design (case-control)
Unger 1999	Wrong study design
Van der Cammen 1992	Wrong setting (secondary care)
Van Exel 2003	No reference standard
Van Sanden 2012	Wrong study design
Vantaa 85+	Wrong study design (case-control; all demented subjects were excluded)
Vas 2001	Wrong study design (case-control; selected population)
Vercambre 2010	Wrong reference test (MMSE is part of the reference standard)
Viglieccа 2012	Wrong study design
Waite 2001	Wrong target condition (cognitive impairment)
Watfa 2001	Wrong study design (case-control; subjects at baseline all in good cognitive health)
Weston 1987	Wrong reference standard (none)
White 2002	Wrong study design (partial verification; only those with positive index tests received reference standard)
Whitney 2012	Wrong setting (secondary care)
Wolf Klein 1989	Wrong setting (secondary care)
Wrobel 2007	Wrong reference standard
Wu 2002	Wrong study design (partial verification; only index test positives received reference standard)
Wu 2003	Wrong study design (no DTA data presented)
Wu 2006	Wrong study design
Yang 2006	Wrong study design (partial verification; only those with positive index test received reference standard)
Yavorsky	Wrong setting (secondary care)

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(*Continued*)

Ylikoski 1992	Wrong study design
Yuseph 1997	Wrong study design (not a DTA study)
Zaragoza study	Wrong reference standard
Zaudig 1992	Wrong study design (case-control)
Zhang 1998	Wrong study design
Zhang 2012	Wrong study design

3MS: Modified Mini-Mental State Examination; **AD**: Alzheimer's disease; **CAMCOG**: Cambridge cognition examination; **CASI**: Cognitive Abilities Screening Instrument; **CDR**: clinical dementia rating; **DSM**: Diagnostic and Statistical Manual of Mental Disorders; **DTA**: diagnostic test accuracy; **MCI**: mild cognitive impairment; **MMSE**: Mini-Mental State Examination.

Characteristics of studies awaiting classification *[ordered by study ID]*

Gungen 2002

Study characteristics	
Patient sampling	No information available
Patient characteristics and setting	-
Index tests	-
Target condition and reference standard(s)	-
Flow and timing	-
Comparative	-
Notes	-

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Jianbo 2013

Study characteristics	
Patient sampling	No information available
Patient characteristics and setting	-
Index tests	-
Target condition and reference standard(s)	-
Flow and timing	-
Comparative	-
Notes	-

Kornsey

Study characteristics	
Patient sampling	No information available
Patient characteristics and setting	-
Index tests	-
Target condition and reference standard(s)	-
Flow and timing	-
Comparative	-
Notes	-

Kvitting 2013

Study characteristics	
Patient sampling	A total of 81 participants (≥ 65 years old and living at home) were recruited from 4 primary health care centres in Sweden between December 2007 and May 2009. Of these patients, 52 exhibited possible cognitive impairment and 29 were presumed cognitively healthy and visiting primary care for some other medical problem. All 81 patients were asked to participate in the study during an appointment with a general practitioner. 1 patient declined

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Kvitting 2013 (*Continued*)

Patient characteristics and setting	48 women (59%) and 33 men, 77 of the 81 were native Swedish speakers, average age 77.2 years, average education 10.4 years, duration of cognitive symptoms 1.5 years
Index tests	MMSE (we presume a Swedish translation. No reference was given to any validation of the translation.)
Target condition and reference standard(s)	Dementia diagnosed according to ICD-10
Flow and timing	-
Comparative	-
Notes	-

Orsi

Study characteristics	
Patient sampling	No information available
Patient characteristics and setting	-
Index tests	-
Target condition and reference standard(s)	-
Flow and timing	-
Comparative	-
Notes	-

Shaaban 2013

Study characteristics	
Patient sampling	"This was a cross-sectional study involving 49 Community dwelling elderly age 65 years and above who attended primary care in Keylantan from January to February 2010. Those who were diagnosed to have Parkinson's disease, mental retardation, psychiatric illness and physical handicaps were excluded."
Patient characteristics and setting	"A total of 49 respondents were involved in this study. Majority of the subjects were Malay (98%) and married (88%)." 64% were female and 61% were educated to primary level. Median age was 68 years. "According to DSM-IV criteria 79.6% were normal and 20.4% had dementia."

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Shaaban 2013 (*Continued*)

Index tests	The Malay version of the MMSE (previously validated)
Target condition and reference standard(s)	Dementia, DSM-IV-TR
Flow and timing	Information on timing is not clearly stated but we assume that the index test and reference standard were conducted on the same day
Comparative	-
Notes	-

Upadhyaya 2010

Study characteristics	
Patient sampling	No information available
Patient characteristics and setting	-
Index tests	-
Target condition and reference standard(s)	-
Flow and timing	-
Comparative	-
Notes	-

Yu 2012

Study characteristics	
Patient sampling	"Three communities from ChaoYang District, 1 community from XiCheng District, and 2 villages from Chang Ping District were then conveniently selected to recruit the participants from. Residents listed in the census of the community registration that were aged 60 and above were contacted for participation. 1056 participants participated in the present study, and 1001 participants were included in the final data analyses based on the following inclusion and exclusion criteria. Inclusion criteria were individuals (1) who were 60 years old or older and registered as permanent residents in their residing district in Beijing (N = 1056), and (2) who completed both the MoCA-BJ and the MMSE (N = 1036). Exclusion criteria were individuals (1) who had missing clinical diagnoses (N = 25), and (2) who had received a clinical diagnosis of depression (N = 10)."

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Yu 2012 (*Continued*)

Patient characteristics and setting	From table 1. Average age 70.66 years, average years of education 10.1 years, average MMSE 25.9. 57.1% female
Index tests	MMSE
Target condition and reference standard(s)	Dementia, DSM IV
Flow and timing	-
Comparative	-
Notes	email sent 24 October to clarify missing information on sampling, case-control, flow and timing

DSM: Diagnostic and Statistical Manual of Mental Disorders; **ICD**: International Classification of Diseases; **MMSE**: Mini-Mental State Examination.

Characteristics of ongoing studies *[ordered by study ID]*

Guiata 2012

Trial name or title	InveCe.Ab study
Target condition and reference standard(s)	Comparative
Index and comparator tests	Comparative
Starting date	Comparative
Contact information	Antonio Guaita MD; GolgiCenci Foundation
Notes	Prevalence study, no diagnostic test accuracy data published yet

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DATA

Presented below are all the data for all of the tests entered into the review.

Tests. Data tables by test

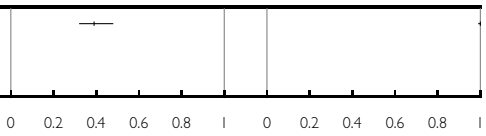
Test	No. of studies	No. of participants
1 MMSE at 14 normality	1	435
2 MMSE at 15 normality	2	935
3 MMSE at 16 normality	1	435
4 MMSE at 17 normality	4	1332
5 MMSE at 18 normality	9	3848
6 MMSE at 19 normality	9	4450
7 MMSE at 20 normality	9	4092
8 MMSE at 21 normality	8	4555
9 MMSE at 22 normality	9	4899
10 MMSE at 23 normality	11	4750
11 MMSE at 24 normality (23/24)	25	12092
12 MMSE at 25 normality	16	6744
13 MMSE at 26 normality	9	5093
14 MMSE at 27 normality	6	4624
15 MMSE at 28 normality	3	2930
16 MMSE at 29 normality	2	691
17 MMSE at 30 normality	1	435
18 MMSE adjusted for education	8	8630
22 MMSE at 10 normality	1	500
23 Main analysis	27	13790

Test 1. MMSE at 14 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 1 MMSE at 14 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity	Sensitivity	Specificity
Kahle-Wrobleski 2007	61	0	94	280	0.39 [0.32, 0.48]	1.00 [0.99, 1.00]		



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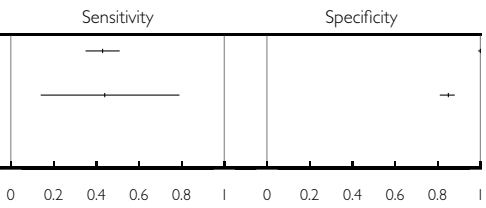
Test 2. MMSE at 15 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 2 MMSE at 15 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Kahle-Wrobleski 2007	66	0	89	280	0.43 [0.35, 0.51]	1.00 [0.99, 1.00]
Phantumchinda 1991	4	74	5	417	0.44 [0.14, 0.79]	0.85 [0.81, 0.88]

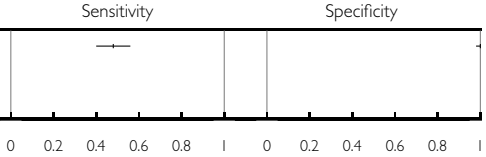


Test 3. MMSE at 16 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 3 MMSE at 16 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Kahle-Wrobleski 2007	74	1	81	279	0.48 [0.40, 0.56]	1.00 [0.98, 1.00]



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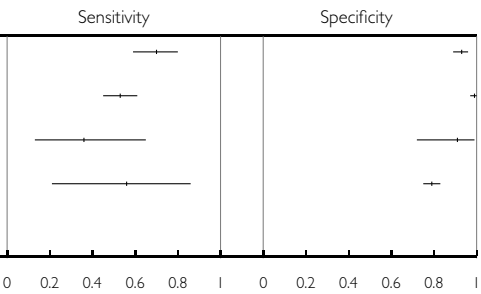
Test 4. MMSE at 17 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 4 MMSE at 17 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Carnero-Pardo 2013	54	20	23	263	0.70 [0.59, 0.80]	0.93 [0.89, 0.96]
Kahle-Wrobleski 2007	82	2	73	278	0.53 [0.45, 0.61]	0.99 [0.97, 1.00]
Kathriarachchi 2005	5	2	9	21	0.36 [0.13, 0.65]	0.91 [0.72, 0.99]
Phantumchinda 1991	5	103	4	388	0.56 [0.21, 0.86]	0.79 [0.75, 0.83]

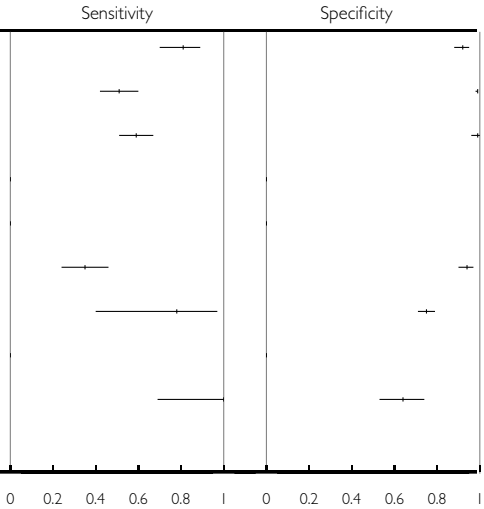


Test 5. MMSE at 18 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 5 MMSE at 18 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Carnero-Pardo 2013	62	23	15	260	0.81 [0.70, 0.89]	0.92 [0.88, 0.95]
Eefsting 1997	63	20	60	2008	0.51 [0.42, 0.60]	0.99 [0.98, 0.99]
Kahle-Wrobleski 2007	91	4	64	276	0.59 [0.51, 0.67]	0.99 [0.96, 1.00]
Keskinoglu 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Lindesay 1997	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Lourenco 2006	27	13	51	212	0.35 [0.24, 0.46]	0.94 [0.90, 0.97]
Phantumchinda 1991	7	123	2	368	0.78 [0.40, 0.97]	0.75 [0.71, 0.79]
Scazufca 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
West Beijing Study 1989	10	32	0	57	1.00 [0.69, 1.00]	0.64 [0.53, 0.74]



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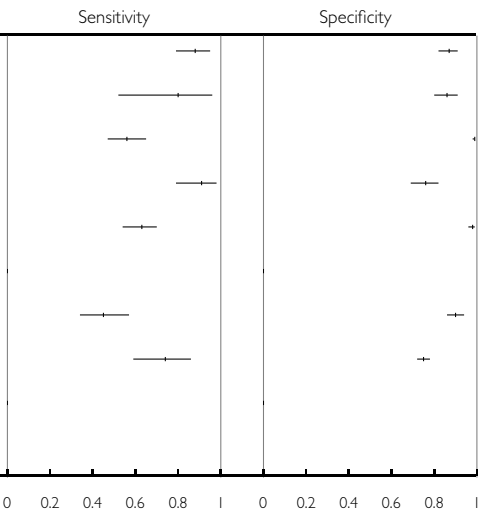
Test 6. MMSE at 19 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 6 MMSE at 19 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Carnero-Pardo 2013	68	37	9	246	0.88 [0.79, 0.95]	0.87 [0.82, 0.91]
Cruz-Orduna 2012	12	20	3	125	0.80 [0.52, 0.96]	0.86 [0.80, 0.91]
Eefsting 1997	69	20	54	2008	0.56 [0.47, 0.65]	0.99 [0.98, 0.99]
Jeong 2004	42	45	4	144	0.91 [0.79, 0.98]	0.76 [0.69, 0.82]
Kahle-Wrobleski 2007	97	5	58	275	0.63 [0.54, 0.70]	0.98 [0.96, 0.99]
Keskinoglu 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Lourenco 2006	35	22	43	203	0.45 [0.34, 0.57]	0.90 [0.86, 0.94]
Pandav 2002	32	192	11	571	0.74 [0.59, 0.86]	0.75 [0.72, 0.78]
Scazufca 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]



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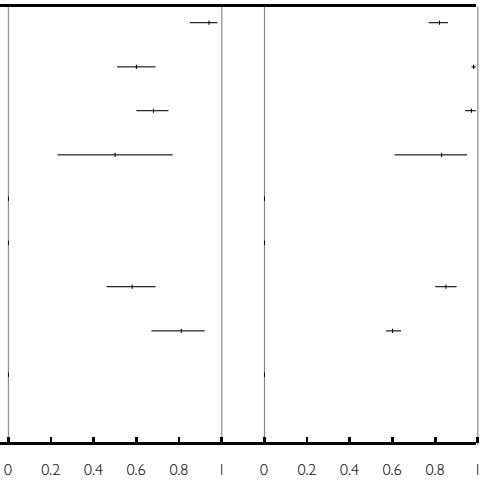
Test 7. MMSE at 20 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 7 MMSE at 20 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Carnero-Pardo 2013	72	51	5	232	0.94 [0.85, 0.98]	0.82 [0.77, 0.86]
Eefsting 1997	74	41	49	1987	0.60 [0.51, 0.69]	0.98 [0.97, 0.99]
Kahle-Wrobleski 2007	105	9	50	271	0.68 [0.60, 0.75]	0.97 [0.94, 0.99]
Kathriarachchi 2005	7	4	7	19	0.50 [0.23, 0.77]	0.83 [0.61, 0.95]
Keskinoglu 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Lindesay 1997	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Lourenco 2006	45	33	33	192	0.58 [0.46, 0.69]	0.85 [0.80, 0.90]
Pandav 2002	35	304	8	459	0.81 [0.67, 0.92]	0.60 [0.57, 0.64]
Scazufca 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]



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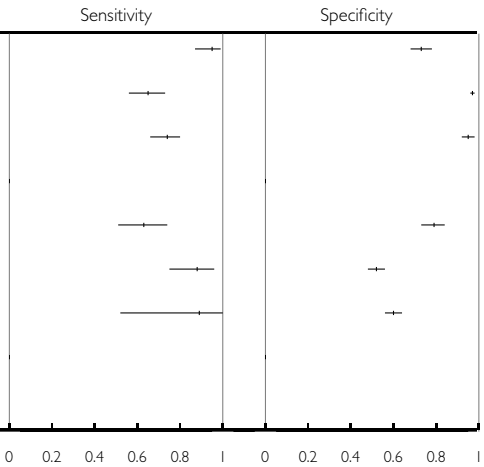
Test 8. MMSE at 21 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 8 MMSE at 21 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Carnero-Pardo 2013	73	76	4	207	0.95 [0.87, 0.99]	0.73 [0.68, 0.78]
Eefsting 1997	80	61	43	1967	0.65 [0.56, 0.73]	0.97 [0.96, 0.98]
Kahle-Wrobleski 2007	114	13	41	267	0.74 [0.66, 0.80]	0.95 [0.92, 0.98]
Keskinoglu 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Lourenco 2006	49	48	29	177	0.63 [0.51, 0.74]	0.79 [0.73, 0.84]
Pandav 2002	38	366	5	397	0.88 [0.75, 0.96]	0.52 [0.48, 0.56]
Phantumchinda 1991	8	196	1	295	0.89 [0.52, 1.00]	0.60 [0.56, 0.64]
Scazufca 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]

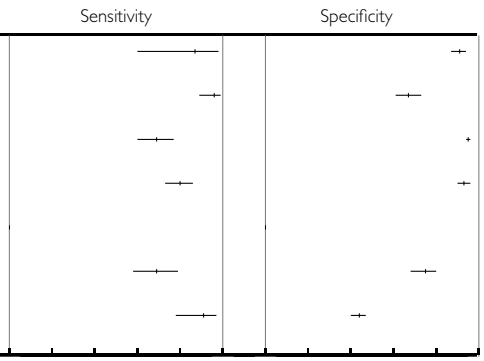


Test 9. MMSE at 22 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 9 MMSE at 22 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Callahan 2002	13	31	2	298	0.87 [0.60, 0.98]	0.91 [0.87, 0.94]
Carnero-Pardo 2013	74	93	3	190	0.96 [0.89, 0.99]	0.67 [0.61, 0.73]
Eefsting 1997	85	101	38	1927	0.69 [0.60, 0.77]	0.95 [0.94, 0.96]
Kahle-Wrobleski 2007	124	19	31	261	0.80 [0.73, 0.86]	0.93 [0.90, 0.96]
Keskinoglu 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Lourenco 2006	54	57	24	168	0.69 [0.58, 0.79]	0.75 [0.68, 0.80]
Pandav 2002	39	429	4	334	0.91 [0.78, 0.97]	0.44 [0.40, 0.47]



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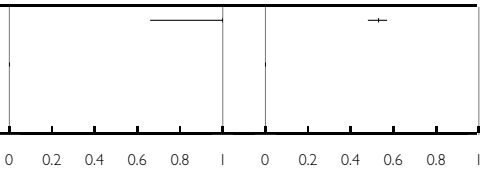
Study	TP	FP	FN	TN	Sensitivity	Specificity
Phantumchinda 1991	9	231	0	260	1.00 [0.66, 1.00]	0.53 [0.48, 0.57]
Scazufca 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]

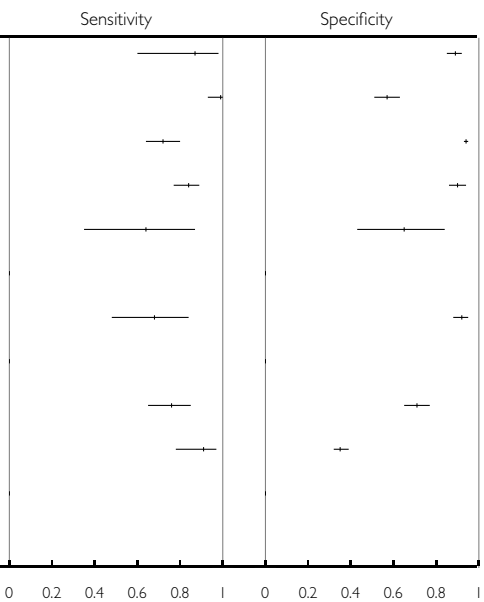


Test 10. MMSE at 23 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 10 MMSE at 23 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Callahan 2002	13	36	2	293	0.87 [0.60, 0.98]	0.89 [0.85, 0.92]
Carnero-Pardo 2013	76	122	1	161	0.99 [0.93, 1.00]	0.57 [0.51, 0.63]
Eefsting 1997	89	122	34	1906	0.72 [0.64, 0.80]	0.94 [0.93, 0.95]
Kahle-Wrobleski 2007	130	27	25	253	0.84 [0.77, 0.89]	0.90 [0.86, 0.94]
Kathriarachchi 2005	9	8	5	15	0.64 [0.35, 0.87]	0.65 [0.43, 0.84]
Keskinoglu 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Lavery 2007	19	23	9	263	0.68 [0.48, 0.84]	0.92 [0.88, 0.95]
Lindesay 1997	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Lourenco 2006	59	65	19	160	0.76 [0.65, 0.85]	0.71 [0.65, 0.77]
Pandav 2002	39	494	4	269	0.91 [0.78, 0.97]	0.35 [0.32, 0.39]
Scazufca 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]



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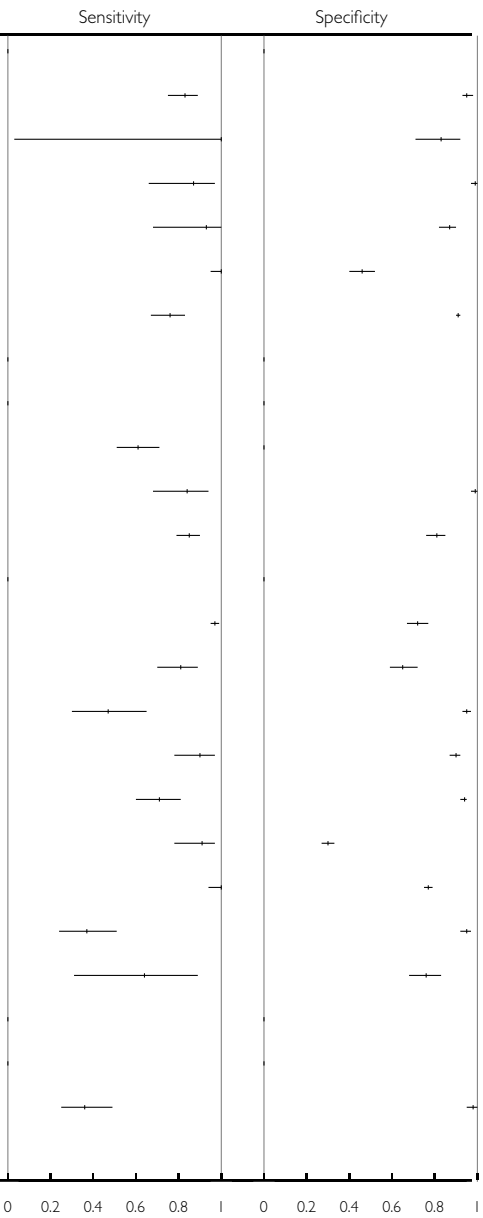
Test 11. MMSE at 24 normality (23/24).

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 11 MMSE at 24 normality (23/24)

Study	TP	FP	FN	TN	Sensitivity	Specificity
ADAMS Study 2007	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Aevarsson 2000	97	14	20	297	0.83 [0.75, 0.89]	0.95 [0.93, 0.98]
Baker 1993	1	9	0	45	1.00 [0.03, 1.00]	0.83 [0.71, 0.92]
Burkart 2000	20	2	3	231	0.87 [0.66, 0.97]	0.99 [0.97, 1.00]
Callahan 2002	14	44	1	285	0.93 [0.68, 1.00]	0.87 [0.82, 0.90]
Carnero-Pardo 2013	77	153	0	130	1.00 [0.95, 1.00]	0.46 [0.40, 0.52]
Eefsting 1997	93	183	30	1845	0.76 [0.67, 0.83]	0.91 [0.90, 0.92]
Fillenbaum 1990	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Frank 1996	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Helsinki Aging Study 1994	57	0	36	0	0.61 [0.51, 0.71]	0.0 [0.0, 0.0]
Heun 1998	31	3	6	248	0.84 [0.68, 0.94]	0.99 [0.97, 1.00]
Kahle-Wrobleski 2007	132	54	23	226	0.85 [0.79, 0.90]	0.81 [0.76, 0.85]
Keskinoglu 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Kungsholmen Study 1992	305	98	9	256	0.97 [0.95, 0.99]	0.72 [0.67, 0.77]
Lourenco 2006	63	78	15	147	0.81 [0.70, 0.89]	0.65 [0.59, 0.72]
Mackinnon 2003	17	31	19	580	0.47 [0.30, 0.65]	0.95 [0.93, 0.97]
Maki 2000	44	61	5	552	0.90 [0.78, 0.97]	0.90 [0.87, 0.92]
MoVies Study 1993	54	63	22	980	0.71 [0.60, 0.81]	0.94 [0.92, 0.95]
Pandav 2002	39	536	4	227	0.91 [0.78, 0.97]	0.30 [0.27, 0.33]
PAQUID Study	64	612	0	2051	1.00 [0.94, 1.00]	0.77 [0.75, 0.79]
Pond 1994	21	16	36	295	0.37 [0.24, 0.51]	0.95 [0.92, 0.97]
Ramlall 2013	7	31	4	98	0.64 [0.31, 0.89]	0.76 [0.68, 0.83]
Rummans 1996	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Scazufca 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Schultz-Larsen 2007	25	3	44	170	0.36 [0.25, 0.49]	0.98 [0.95, 1.00]



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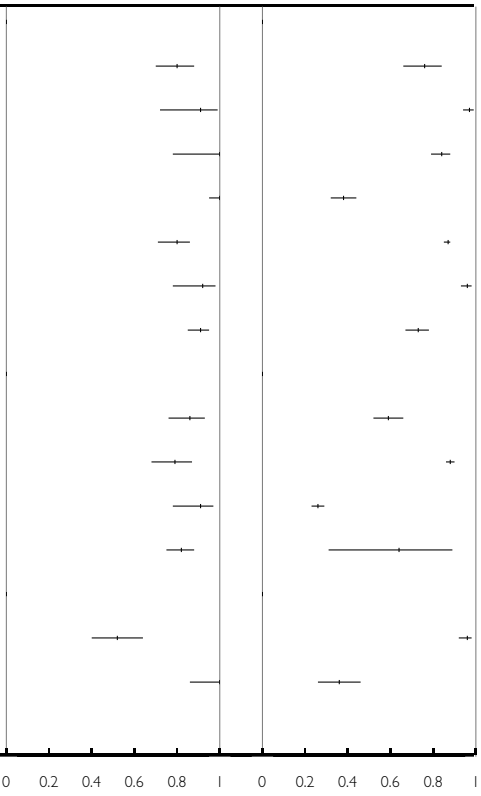
Test 12. MMSE at 25 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 12 MMSE at 25 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
AMSTEL Study 1997	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Brodaty 2002	66	23	16	71	0.80 [0.70, 0.88]	0.76 [0.66, 0.84]
Burkart 2000	21	7	2	226	0.91 [0.72, 0.99]	0.97 [0.94, 0.99]
Callahan 2002	15	53	0	276	1.00 [0.78, 1.00]	0.84 [0.79, 0.88]
Carnero-Pardo 2013	77	175	0	108	1.00 [0.95, 1.00]	0.38 [0.32, 0.44]
Eefsting 1997	98	264	25	1764	0.80 [0.71, 0.86]	0.87 [0.85, 0.88]
Heun 1998	34	10	3	240	0.92 [0.78, 0.98]	0.96 [0.93, 0.98]
Kahle-Wrobleski 2007	141	76	14	204	0.91 [0.85, 0.95]	0.73 [0.67, 0.78]
Keskinoglu 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Lourenco 2006	67	92	11	133	0.86 [0.76, 0.93]	0.59 [0.52, 0.66]
MoVies Study 1993	60	126	16	917	0.79 [0.68, 0.87]	0.88 [0.86, 0.90]
Pandav 2002	39	567	4	196	0.91 [0.78, 0.97]	0.26 [0.23, 0.29]
Ramlall 2013	115	4	25	7	0.82 [0.75, 0.88]	0.64 [0.31, 0.89]
Scazufca 2009	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Schultz-Larsen 2007	36	7	33	166	0.52 [0.40, 0.64]	0.96 [0.92, 0.98]
Winblad 2010	24	58	0	32	1.00 [0.86, 1.00]	0.36 [0.26, 0.46]



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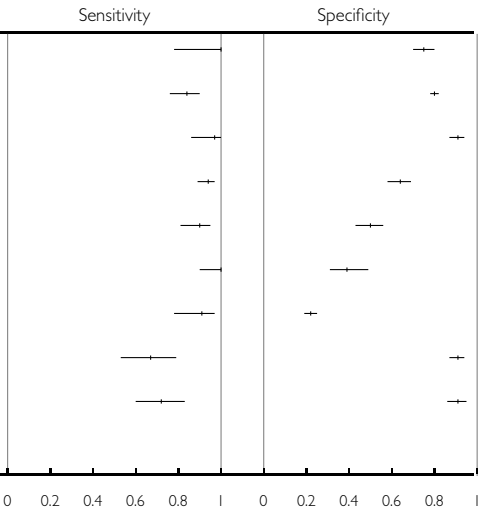
Test 13. MMSE at 26 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 13 MMSE at 26 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Callahan 2002	15	82	0	247	1.00 [0.78, 1.00]	0.75 [0.70, 0.80]
Eefsting 1997	103	406	20	1622	0.84 [0.76, 0.90]	0.80 [0.78, 0.82]
Heun 1998	36	23	1	228	0.97 [0.86, 1.00]	0.91 [0.87, 0.94]
Kahle-Wrobleski 2007	146	102	9	178	0.94 [0.89, 0.97]	0.64 [0.58, 0.69]
Lourenco 2006	70	113	8	112	0.90 [0.81, 0.95]	0.50 [0.43, 0.56]
Macedo Montano 2005	34	74	0	48	1.00 [0.90, 1.00]	0.39 [0.31, 0.49]
Pandav 2002	39	593	4	170	0.91 [0.78, 0.97]	0.22 [0.19, 0.25]
Pond 1994	38	28	19	283	0.67 [0.53, 0.79]	0.91 [0.87, 0.94]
Schultz-Larsen 2007	50	15	19	158	0.72 [0.60, 0.83]	0.91 [0.86, 0.95]

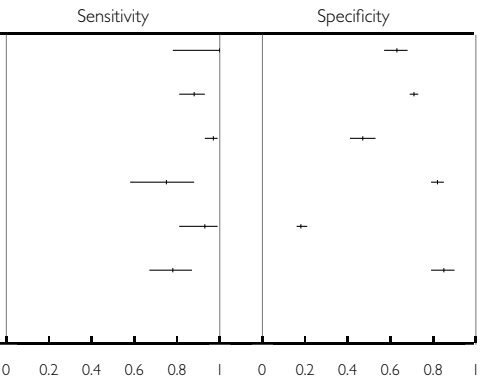


Test 14. MMSE at 27 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 14 MMSE at 27 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Callahan 2002	15	123	0	206	1.00 [0.78, 1.00]	0.63 [0.57, 0.68]
Eefsting 1997	108	588	15	1440	0.88 [0.81, 0.93]	0.71 [0.69, 0.73]
Kahle-Wrobleski 2007	150	149	5	131	0.97 [0.93, 0.99]	0.47 [0.41, 0.53]
Mackinnon 2003	27	110	9	500	0.75 [0.58, 0.88]	0.82 [0.79, 0.85]
Pandav 2002	40	624	3	139	0.93 [0.81, 0.99]	0.18 [0.16, 0.21]
Schultz-Larsen 2007	54	26	15	147	0.78 [0.67, 0.87]	0.85 [0.79, 0.90]



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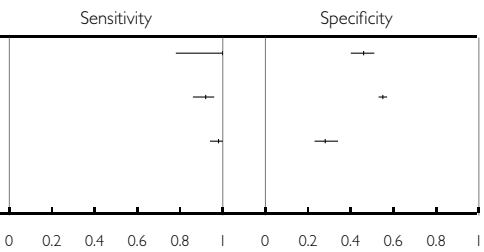
Test 15. MMSE at 28 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 15 MMSE at 28 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Callahan 2002	15	179	0	150	1.00 [0.78, 1.00]	0.46 [0.40, 0.51]
Eefsting 1997	113	913	10	1115	0.92 [0.86, 0.96]	0.55 [0.53, 0.57]
Kahle-Wrobleski 2007	152	201	3	79	0.98 [0.94, 1.00]	0.28 [0.23, 0.34]

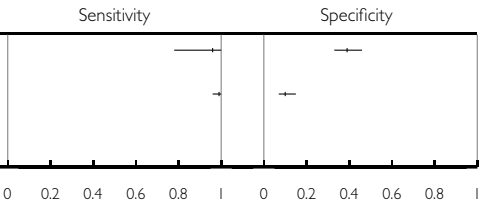


Test 16. MMSE at 29 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 16 MMSE at 29 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Burkart 2000	22	142	1	91	0.96 [0.78, 1.00]	0.39 [0.33, 0.46]
Kahle-Wrobleski 2007	154	251	1	29	0.99 [0.96, 1.00]	0.10 [0.07, 0.15]



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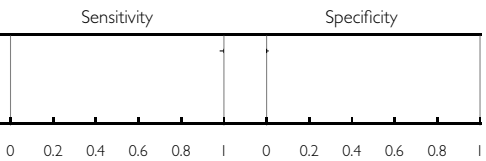
Test 17. MMSE at 30 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 17 MMSE at 30 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Kahle-Wrobleski 2007	155	280	0	0	1.00 [0.98, 1.00]	0.0 [0.0, 0.01]

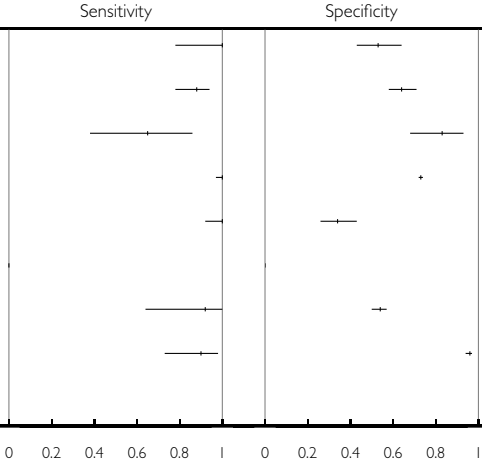


Test 18. MMSE adjusted for education.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 18 MMSE adjusted for education

Study	TP	FP	FN	TN	Sensitivity	Specificity
Correira 2001	15	44	0	50	1.00 [0.78, 1.00]	0.53 [0.43, 0.64]
Iavarone 2006	66	78	9	141	0.88 [0.78, 0.94]	0.64 [0.58, 0.71]
Jacinto 2011	11	7	6	34	0.65 [0.38, 0.86]	0.83 [0.68, 0.93]
Lam 2008	143	1614	0	4343	1.00 [0.97, 1.00]	0.73 [0.72, 0.74]
Liu 1996a	45	86	0	44	1.00 [0.92, 1.00]	0.34 [0.26, 0.43]
Mingyuan 1998	0	0	0	0	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Rosselli 2000	12	315	1	365	0.92 [0.64, 1.00]	0.54 [0.50, 0.57]
Tang 1999	26	51	3	1121	0.90 [0.73, 0.98]	0.96 [0.94, 0.97]



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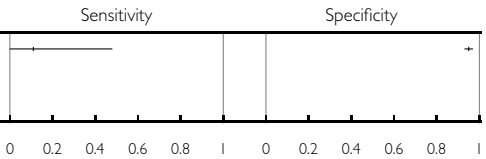
Test 22. MMSE at 10 normality.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 22 MMSE at 10 normality

Study	TP	FP	FN	TN	Sensitivity	Specificity
Phantumchinda 1991	1	25	8	466	0.11 [0.00, 0.48]	0.95 [0.93, 0.97]

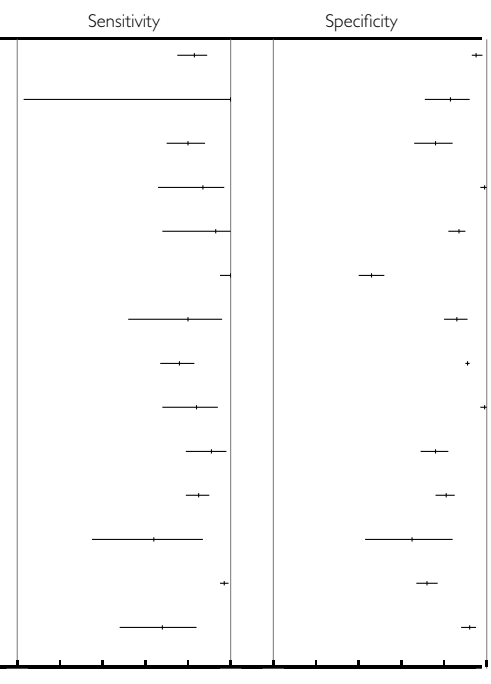


Test 23. Main analysis.

Review: Mini-Mental State Examination (MMSE) for the detection of dementia in clinically unevaluated people aged 65 and over in community and primary care populations

Test: 23 Main analysis

Study	TP	FP	FN	TN	Sensitivity	Specificity
Aevarsson 2000	97	14	20	297	0.83 [0.75, 0.89]	0.95 [0.93, 0.98]
Baker 1993	1	9	0	45	1.00 [0.03, 1.00]	0.83 [0.71, 0.92]
Brodaty 2002	66	23	16	71	0.80 [0.70, 0.88]	0.76 [0.66, 0.84]
Burkart 2000	20	2	3	231	0.87 [0.66, 0.97]	0.99 [0.97, 1.00]
Callahan 2002	14	44	1	285	0.93 [0.68, 1.00]	0.87 [0.82, 0.90]
Carnero-Pardo 2013	77	153	0	130	1.00 [0.95, 1.00]	0.46 [0.40, 0.52]
Cruz-Orduna 2012	12	20	3	125	0.80 [0.52, 0.96]	0.86 [0.80, 0.91]
Eefsting 1997	93	183	30	1845	0.76 [0.67, 0.83]	0.91 [0.90, 0.92]
Heun 1998	31	3	6	248	0.84 [0.68, 0.94]	0.99 [0.97, 1.00]
Jeong 2004	42	45	4	144	0.91 [0.79, 0.98]	0.76 [0.69, 0.82]
Kahle-Wrobleski 2007	132	54	23	226	0.85 [0.79, 0.90]	0.81 [0.76, 0.85]
Kathriarachchi 2005	9	8	5	15	0.64 [0.35, 0.87]	0.65 [0.43, 0.84]
Kungsholmen Study 1992	305	98	9	256	0.97 [0.95, 0.99]	0.72 [0.67, 0.77]
Lavery 2007	19	23	9	263	0.68 [0.48, 0.84]	0.92 [0.88, 0.95]



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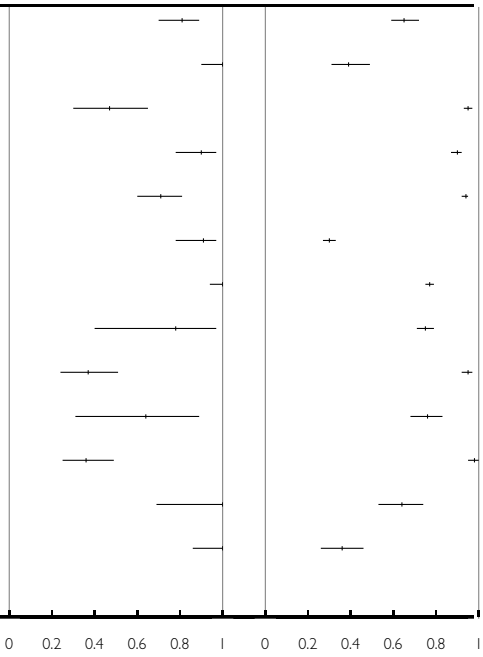
Study	TP	FP	FN	TN	Sensitivity	Specificity
Lourenco 2006	63	78	15	147	0.81 [0.70, 0.89]	0.65 [0.59, 0.72]
Macedo Montano 2005	34	74	0	48	1.00 [0.90, 1.00]	0.39 [0.31, 0.49]
Mackinnon 2003	17	31	19	580	0.47 [0.30, 0.65]	0.95 [0.93, 0.97]
Maki 2000	44	61	5	552	0.90 [0.78, 0.97]	0.90 [0.87, 0.92]
MoVies Study 1993	54	63	22	980	0.71 [0.60, 0.81]	0.94 [0.92, 0.95]
Pandav 2002	39	536	4	227	0.91 [0.78, 0.97]	0.30 [0.27, 0.33]
PAQUID Study	64	612	0	2051	1.00 [0.94, 1.00]	0.77 [0.75, 0.79]
Phantumchinda 1991	7	123	2	368	0.78 [0.40, 0.97]	0.75 [0.71, 0.79]
Pond 1994	21	16	36	295	0.37 [0.24, 0.51]	0.95 [0.92, 0.97]
Ramlall 2013	7	31	4	98	0.64 [0.31, 0.89]	0.76 [0.68, 0.83]
Schultz-Larsen 2007	25	3	44	170	0.36 [0.25, 0.49]	0.98 [0.95, 1.00]
West Beijing Study 1989	10	32	0	57	1.00 [0.69, 1.00]	0.64 [0.53, 0.74]
Winblad 2010	24	58	0	32	1.00 [0.86, 1.00]	0.36 [0.26, 0.46]



ADDITIONAL TABLES

Table 1. Summary of included community studies

Study	Number of citations[a]	Sample size	Number of people with dementia	Prevalence of dementia	Reference standard	Reported MMSE cut points indicating normal
Studies where 2 x 2 data was available						
Aevarsson 2000	1	428	117	27.3%	DSM-III	24
Baker 1993	1	55	1	1.8%	DSM-III-R	24
Burkart 2000	1	256	23	9.0%	DSM-III-R	24, 25, 29
Callahan 2002	1	344	15	4.6%	DSM-III-R	22, 23, 24, 25, 26, 27, 28
Correira 2001	1	109	15	13.8%	DSM-IV	Adjusted for education

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Table 1. Summary of included community studies (*Continued*)

Eefsting 1997	1	2151	123	5.7%	DSM-III-R	18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28
Heun 1998	1	287	37	12.9%	DSM-III-R	24, 25, 26
Iavarone 2006	1	294	75	25.5%	DSM-IV	Adjusted for education
Jacinto 2011	1	58	17	29.3%	DSM-IV	Adjusted for education
Jeong 2004	1	235	46	19.6%	DSM-IV	19
Kahle-Wrobleski 2007	1	435	157	36.0%	DSM-IV	14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30
Kathriarachchi 2005	1	37	17	38.0%	CDR	17, 20, 23
Kungsholmen Study 1992	7	668	314	47.0%	DSM-III-R	24
Macedo Montano 2005	1	156	34	21.8%	DSM-IV-R	26
Mackinnon 2003	1	646	36	5.6%	DSM-III-R	24, 27
Maki 2000	1	662	49	7.4%	DSM-III-R	24
MoVies Study 1993	5	1119	76	6.8%	DSM-III-R	24, 25
Lam 2008	1	5957	143	2.4%	DSM-IV	Adjusted for education
Liu 1996a	1	130	45	34.6%	DSM-III	Adjusted for education
Pandav 2002	1	806	43	5.3%	DSM-III-R	19, 20, 21, 22, 23, 24, 25, 26, 27
PAQUID Study	5	2730	101	3.7%	DSM-III	24
Phantumchinda 1991	1	500	9	1.8%	DSM-III	10, 15, 17, 18, 21, 22

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Table 1. Summary of included community studies (*Continued*)

Ramlall 2013	1	140	11	7.9%	DSM-IV-R	24, 25
Rosselli 2000	1	693	13	1.9%	DSM-IV	Adjusted for education
Schultz-Larsen 2007	1	242	69	28.5%	DSM-IV	24, 25, 26, 27
Tang 1999	1	1201	29	2.4%	DSM-III-R	Adjusted for education
West Beijing Study 1989.	2	99	10	10.1	DSM-III	18
Winblad 2010	1	114	24	21.1%	DSM-IV	25
Studies where 2 x 2 data was not available						
ADAMS Study 2007	3	509	129	25.3%	DSM-IV	-
AMSTEL Study 1997	4	4123	261	6.3%	DSM-III-R	-
Fichter 1995	1	402	85	21.2%	DSM-III-R	-
Fillenbaum 1990	1	4164	26	0.6%	DSM-III-R	-
Frank 1996	1	380	56	14.7%	NINCDS-ADRDA	-
Helsinki Aging Study 1994[b]	2	656	93	14.2%	DSM-III-R	-
Keskinoglu 2009	1	490	63	12.9%	DSM-III	-
Lee 2002	1	643	40	6.2%	DSM-III	-
Li 2006	1	144	19	13.1%	DSM-III	-
Lindesay 1997	1	297	Not reported	Not reported	DSM-III	-
Mingyuan 1998	1	Not reported	Not reported	Not reported	DSM-III-R	-
Rummans 1996	1	201	21	10.4%	DSM-III-R	-
Scazufca 2009	1	1933	84	4.3%	DSM-IV	-

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Table 1. Summary of included community studies (*Continued*)

Wilder 1995	1	795	Not reported	-	DSM-III	-

CDR: clinical dementia rating; **DSM**: Diagnostic and Statistical Manual of Mental Disorders; **NINCDS-ADRDA**: National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association.
[a] Refers to the number of citations that we retrieved that refer to the same study and are listed in Included studies.
[b] Study reported sensitivity only and so could not be included in meta-analysis in absence of paired data.

Table 2. Summary of included primary care studies

Study	Number of citations[a]	Sample size	Number of people with dementia	Prevalence of dementia	Reference standard	Reported MMSE cut points indicating normal
Setting: asymptomatic primary care						
Brodaty 2002	1	176	82	46.6%	DSM-IV	25
Lavery 2007	1	313	28	8.9%	CDR	23
Lourenco 2006	1	303	78	25.7%	DSM-IV	18, 19, 20, 21, 22, 23, 24, 25, 26
Pond 1994	1	367	57	15.5%	DSM-III-R	24, 26
Setting: symptomatic primary care						
Carnero-Pardo 2013	3	360	77	21.4%	DSM-IV-R	17, 18, 19, 20, 21, 22, 23, 24, 25
Cruz-Orduna 2012	1	160	15	9.4%	DSM-IV-R	19

CDR: clinical dementia rating; **DSM**: Diagnostic and Statistical Manual of Mental Disorders.
[a] Refers to the number of citations that we retrieved that refer to the same study and are listed in Included studies.

Table 3. Papers included in Mitchell 2009 review but not in this review

Citation	Setting and sample	Prevalence of dementia	Index Test	Cut point indicating normal	Reference Standard	Sensitivity	Specificity	Reason for exclusion from this review
Belle 2000	MoVies Study 1993 Community age-strati-	68 dementia and 1110 no dementia	MMSE	27	Short and Sweet Screening	96%	78%	No mention of MMSE in abstract and

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Table 3. Papers included in Mitchell 2009 review but not in this review (*Continued*)

	fied random sample				Instrument			wrong reference standard in this paper but data from study (from another paper) included in our review
Brayne 1989	Community Stratified random sample of 365 women aged 70-79 years	29 dementia 336 no dementia	MMSE	22	CAMDEX	83%	87%	No mention of MMSE in abstract and wrong reference standard
Clarke 1991	Community Total sample of all people aged over 75 years on 1 GP list	265 dementia, 150 no dementia	MMSE	22	CAMDEX	77%	71%	Wrong reference standard
Cullen 2005	Community Sample of people aged over 65 years from GP lists	44 dementia 1071 no dementia	MMSE	24	AGECAT	91%	87%	Wrong reference standard
Hooijer 1992	AMSTEL Study 1997 All elderly patients of 1 Amsterdam GP	13 dementia 345 no dementia	MMSE	24	CAMDEX	77%	97%	Wrong reference standard in this paper but data from study (from another paper) included in our review
O'Connor 1989	Community Total sample of all people aged over 75 on 5 GP lists	196 dementia 285 no dementia	MMSE	24	CAMDEX	86%	92%	Wrong reference standard
Wind 1997	AMSTEL Study 1997 Age stratified sam-	114 dementia 419 no dementia	MMSE	24	AGECAT	69%	89%	Wrong reference standard in this paper

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Table 3. Papers included in Mitchell 2009 review but not in this review (*Continued*)

	ple of participating practices in AMSTEL							but data from study (from another paper) included in our review
Huppert 2005	Community MRC-CFAS study Random, age-stratified sampling of people aged over 65 years	795 dementia 11,885 no dementia	MMSE	23	AGECAT	88%	92%	Wrong reference standard, abstract makes no mention of diagnostic accuracy and diagnostic accuracy terms such as sensitivity and specificity do not appear in the paper

APPENDICES

Appendix 1. Classification of dementia

World Health Organization International Classification of Diseases-10

G1. Evidence of each of the following:

- A decline in memory, which is most evident in the learning of new information, although in more severe cases, the recall of previously learned information also may be affected. The impairment applies to both verbal and nonverbal material. The decline should be objectively verified by obtaining a reliable history from an informant, supplemented, if possible, by neuropsychological tests or quantified cognitive assessments.
- A decline in other cognitive abilities characterised by deterioration in judgement and thinking, such as planning and organising, and in the general processing of information. Evidence for this should be obtained when possible by interviewing an informant, supplemented, if possible, by neuropsychological tests or quantified objective assessments. Deterioration from a previously higher level of performance should be established.

G2. Preserved awareness of the environment during a period long enough to enable the unequivocal demonstration of G1. When episodes of delirium are superimposed, the diagnosis of dementia should be deferred.

G3. A decline in emotional control or motivation, or a change in social behaviour, manifest as at least one of the following.

- Emotional liability.
- Irritability.
- Apathy.
- Coarsening of social behaviour.

G4. For a confident clinical diagnosis, G1 should have been present for at least six months; if the period since the manifest onset is shorter, the diagnosis can only be tentative.

Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision

A. The development of multiple cognitive deficits manifested by both:

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1. memory impairment (impaired ability to learn new information or to recall previously learned information;
2. one (or more) of the following cognitive disturbances.
    - Aphasia (language disturbance).
    - Apraxia (impaired ability to carry out motor activities despite intact motor function).
    - Agnosia (failure to recognise or identify objects despite intact sensory function).
    - Disturbance in executive functioning (i.e. planning, organizing, sequencing, abstracting).

B. Each of the cognitive deficits in Criteria A1 and A2

- Causes significant impairment in social or occupational functioning.
- Represents a significant decline from a previous level of functioning.

C. The deficits do not occur exclusively during the course of a delirium.
D. The disturbance is not better accounted for by another Axis I disorder (e.g. major depressive disorder, schizophrenia).

Appendix 2. Sources searched and search strategies

Source	Search strategy	Hits retrieved
1. MEDLINE In-process and other non-indexed citations and MEDLINE 1950-present (Ovid SP) **Most recent search: 20 May 2014**	1. MMSE*.ti,ab. 2. sMMSE.ti,ab. 3. Folstein*.ti,ab. 4. MiniMental.ti,ab. 5. "mini mental stat*".ti,ab. 6. or/1-5	Nov 2012: 10048 May 2014: 1657
2. EMBASE 1980-2012 November 16 (Ovid SP) **Most recent search: 20 May 2014**	1. MMSE*.ti,ab. 2. sMMSE.ti,ab. 3. Folstein*.ti,ab. 4. MiniMental.ti,ab. 5. "mini mental stat*".ti,ab. 6. 3MS.ti,ab. 7. *mini mental state examination/ 8. or/1-7 9. dement*.ti,ab. 10. alzheimer*.ti,ab. 11. exp *dementia/ 12. "vascular cognitive impair*".ti,ab. 13. ("lewy bod*" or DLB or LBD).ti,ab. 14. (AD or VaD or FTLD or FTD or DLB or LDB).ti,ab. 15. delirium/ 16. deliri*.ti,ab. 17. or/9-16 18. exp *mild cognitive impairment/ 19. "cognit* impair*".ti,ab. 20. (forgetful* or confused or confusion).ti,ab. 21. MCI.ti,ab. 22. ACMI.ti,ab.	Nov 2012: 11675 May 2014: 2774

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(*Continued*)

	23. ARCD.ti,ab. 24. SMC.ti,ab. 25. CIND.ti,ab. 26. BSF.ti,ab. 27. AAMI.ti,ab. 28. LCD.ti,ab. 29. QD.ti,ab. 30. AACD.ti,ab. 31. MNCD.ti,ab. 32. MCD.ti,ab. 33. (nMCI or aMCI or mMCI).ti,ab. 34. ("N-MCI" or "A-MCI" or "M-MCI") .ti,ab. 35. "Petersen criteria".ab. 36. ((CDR adj2 "0.5") or ("clinical dementia rating" adj3 "0.5")).ab 37. "cognit* declin*".ti,ab. 38. "cognit* deficit*".ti,ab. 39. or/18-38 40. 17 or 39 41. 8 and 40	
3. PsycINFO 1806-November week 2 2012 (Ovid SP) **Most recent search: 20 May 2014**	1. exp Dementia/ 2. exp Delirium/ 3. exp Huntingtons Disease/ 4. exp Kluver Bucy Syndrome/ 5. exp Wernickes Syndrome/ 6. exp Cognitive Impairment/ 7. dement*.mp. 8. alzheimer*.mp. 9. (lewy* adj2 bod*).mp. 10. deliri*.mp. 11. (chronic adj2 cerebrovascular).mp. 12. ("organic brain disease" or "organic brain syndrome").mp 13. "supranuclear palsy".mp. 14. ("normal pressure hydrocephalus" and "shunt*").mp. 15. "benign senescent forgetfulness".mp. 16. (cerebr* adj2 deteriorat*).mp. 17. (cerebral* adj2 insufficient*).mp. 18. (pick* adj2 disease).mp. 19. (creutzfeldt or jcd or cjd).mp. 20. huntington*.mp. 21. binswanger*.mp. 22. korsako*.mp. 23. ("parkinson* disease dementia" or PDD or "parkinson* dementia").mp 24. or/1-23	Nov 2012: 5740 May 2014: 728

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(*Continued*)

	25. "cognit* impair*".mp. 26. exp Cognitive Impairment/ 27. MCI.ti,ab. 28. ACMI.ti,ab. 29. ARCD.ti,ab. 30. SMC.ti,ab. 31. CIND.ti,ab. 32. BSF.ti,ab. 33. AAMI.ti,ab. 34. MD.ti,ab. 35. LCD.ti,ab. 36. QD.ti,ab. 37. AACD.ti,ab. 38. MNCD.ti,ab. 39. MCD.ti,ab. 40. ("N-MCI" or "A-MCI" or "M-MCI").ti,ab. 41. ((cognit* or memory or cerebr* or mental*) adj3 (declin* or impair* or los* or deteriorat* or degenerat* or complain* or disturb* or disorder*)).ti,ab 42. "preclinical AD".mp. 43. "pre-clinical AD".mp. 44. ("preclinical alzheimer*" or "pre-clinical alzheimer*").mp 45. (aMCI or MCIa).ti,ab. 46. ("CDR 0.5" or "clinical dementia rating scale 0.5").ti,ab 47. ("GDS 3" or "stage 3 GDS").ti,ab. 48. ("global deterioration scale" and "stage 3").mp. 49. "Benign senescent forgetfulness".ti,ab. 50. "mild neurocognit* disorder*".ti,ab. 51. (prodrom* adj2 dement*).ti,ab. 52. "age-related symptom*".mp. 53. (episodic adj2 memory).mp. 54. ("pre-clinical dementia" or "preclinical dementia").mp. 55. or/25-54 56. 24 or 55 57. mini mental state examination/ 58. "mini mental stat*".ti,ab. 59. MiniMental.ti,ab. 60. Folstein*.ti,ab. 61. sMMSE.ti,ab. 62. MMSE*.ti,ab. 63. or/57-62 64. 56 and 63	

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(*Continued*)

4. Biosis previews 1926 to present (Thomson Reuters Web of Science) **Most recent search: 20 May 2014**	Topic=(MMSE OR sMMSE OR "mini mental stat*" OR folstein* OR MiniMental) AND Topic=(detect* OR diagnos* OR predict* OR identify OR validity OR validation OR validate OR utility OR sensitivity OR specificity OR screen* OR preval* OR incidence) AND Topic=(dement* OR alzheimer* OR cognitive OR cognition OR memory OR MCI OR petersen) Timespan=All Years. Databases=BIOSIS Previews. Lemmatization=On	Nov 2012: 5713 May 2014: 609
5. Web of Science Core Collection, including the Science Citation Index and the Conference Proceedings Citation Index (Thomson Reuters Web of Science) **Most recent search: 20 May 2014**	Topic=(MMSE OR sMMSE OR "mini mental stat*" OR folstein* OR MiniMental) AND Topic=(detect* OR diagnos* OR predict* OR identify OR validity OR validation OR validate OR utility OR sensitivity OR specificity OR screen* OR preval* OR incidence) AND Topic=(dement* OR alzheimer* OR cognitive OR cognition OR memory OR MCI OR petersen) Timespan=1975- 01-01 - 2012-11-20. Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Lemmatization=On	Nov 2012: 7337 May 2014: 992
6. LILACS (BIREME) **Most recent search: 20 May 2014**	MMSE OR folstein OR "mini mental stat$" OR sMMSE OR MiniMental [Words]	Nov 2012: 224 May 2014: 28
7. ALOIS (CDCIG specialized register searched via the Cochrane Register of Studies) **Most recent search: 20 May 2014**	Index test field: MMSE The Dementia group register is based on a regular search of MEDLINE for diagnostic test accuracy studies using the strategy below. Relevant citations identified are then looked at in full and the healthcare condition of interest and index test/s are extracted and entered into the register 1. "word recall".ti,ab. 2. ("7-minute screen" OR "seven-minute screen").ti,ab. 3. ("6 item cognitive impairment test" OR "six-item cognitive impairment test").ti,ab 4. "6 CIT".ti,ab. 5. "AB cognitive screen".ti,ab. 6. "abbreviated mental test".ti,ab. 7. "ADAS-cog".ti,ab. 8. AD8.ti,ab.	Nov 2012: 251 May 2014: 31

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	9. "inform* interview".ti,ab. 10. "animal fluency test".ti,ab. 11. "brief alzheimer* screen".ti,ab. 12. "brief cognitive scale".ti,ab. 13. "clinical dementia rating scale".ti,ab. 14. "clinical dementia test".ti,ab. 15. "community screening interview for dementia".ti,ab. 16. "cognitive abilities screening instrument".ti,ab. 17. "cognitive assessment screening test".ti,ab. 18. "cognitive capacity screening examination".ti,ab. 19. "clock drawing test".ti,ab. 20. "deterioration cognitive observee".ti,ab. 21. ("Dem Tect" OR DemTect).ti,ab. 22. "object memory evaluation".ti,ab. 23. "IQCODE".ti,ab. 24. "mattis dementia rating scale".ti,ab. 25. "memory impairment screen".ti,ab. 26. "minnesota cognitive acuity screen".ti,ab. 27. "mini-cog".ti,ab. 28. "mini-mental state exam*".ti,ab. 29. "mmse".ti,ab. 30. "modified mini-mental state exam".ti,ab. 31. "3MS".ti,ab. 32. "neurobehavio?ral cognitive status exam*".ti,ab. 33. "cognistat".ti,ab. 34. "quick cognitive screening test".ti,ab. 35. "QCST".ti,ab. 36. "rapid dementia screening test".ti,ab. 37. "RDST".ti,ab. 38. "repeatable battery for the assessment of neuropsychological status".ti,ab 39. "RBANS".ti,ab. 40. "rowland universal dementia assessment scale".ti,ab. 41. "rudas".ti,ab. 42. "self-administered gerocognitive exam*".ti,ab. 43. ("self-administered" and "SAGE").ti,ab 44. "self-administered computerized	

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(*Continued*)

	screening test for dementia".ti,ab 45. "short and sweet screening instrument".ti,ab. 46. "sassi".ti,ab. 47. "short cognitive performance test".ti,ab. 48. "syndrome kurztest".ti,ab. 49. ("six item screener" OR "6-item screener").ti,ab. 50. "short memory questionnaire".ti,ab. 51. ("short memory questionnaire" and "SMQ").ti,ab. 52. "short orientation memory concentration test".ti,ab. 53. "s-omc".ti,ab. 54. "short blessed test".ti,ab. 55. "short portable mental status questionnaire".ti,ab. 56. "spmsq".ti,ab. 57. "short test of mental status".ti,ab. 58. "telephone interview of cognitive status modified".ti,ab 59. "tics-m".ti,ab. 60. "trail making test".ti,ab. 61. "verbal fluency categories".ti,ab. 62. "WORLD test".ti,ab. 63. "general practitioner assessment of cognition".ti,ab. 64. "GPCOG".ti,ab. 65. "Hopkins verbal learning test".ti,ab. 66. "HVLT".ti,ab. 67. "time and change test".ti,ab. 68. "modified world test".ti,ab. 69. "symptoms of dementia screener".ti,ab. 70. "dementia questionnaire".ti,ab. 71. "7MS".ti,ab. 72. ("concord informant dementia scale" or CIDS).ti,ab. 73. (SAPH or "dementia screening and perceived harm*").ti,ab 74. or/1-73 75. exp Dementia/ 76. Delirium, Dementia, Amnestic, Cognitive Disorders/ 77. dement*.ti,ab. 78. alzheimer*.ti,ab. 79. AD.ti,ab. 80. ("lewy bod*" or DLB or LBD or FTD	

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(*Continued*)

	or FTLD or "frontotemporal lobar degeneration" or "frontaltemporal dement*).ti,ab 81. "cognit* impair*".ti,ab. 82. (cognit* adj4 (disorder* or declin* or fail* or function* or degenerat* or deteriorat*)).ti,ab 83. (memory adj3 (complain* or declin* or function* or disorder*)).ti,ab 84. or/75-83 85. exp "sensitivity and specificity"/ 86. "reproducibility of results"/ 87. (predict* adj3 (dement* or AD or alzheimer*)).ti,ab. 88. (identif* adj3 (dement* or AD or alzheimer*)).ti,ab. 89. (discriminat* adj3 (dement* or AD or alzheimer*)).ti,ab. 90. (distinguish* adj3 (dement* or AD or alzheimer*)).ti,ab. 91. (differenti* adj3 (dement* or AD or alzheimer*)).ti,ab. 92. diagnos*.ti. 93. di.fs. 94. sensitivit*.ab. 95. specificit*.ab. 96. (ROC or "receiver operat*").ab. 97. Area under curve/ 98. ("Area under curve" or AUC).ab. 99. (detect* adj3 (dement* or AD or alzheimer*)).ti,ab. 100. sROC.ab. 101. accura*.ti,ab. 102. (likelihood adj3 (ratio* or function*)).ab. 103. (conver* adj3 (dement* or AD or alzheimer*)).ti,ab. 104. ((true or false) adj3 (positive* or negative*)).ab. 105. ((positive* or negative* or false or true) adj3 rate*).ti,ab 106. or/85-105 107. exp dementia/di 108. Cognition Disorders/di [Diagnosis] 109. Memory Disorders/di 110. or/107-109 111. *Neuropsychological Tests/ 112. *Questionnaires/ 113. Geriatric Assessment/mt	

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(*Continued*)

	114. *Geriatric Assessment/ 115. Neuropsychological Tests/mt, st 116. "neuropsychological test*".ti,ab. 117. (neuropsychological adj (assess* or evaluat* or test*)).ti,ab 118. (neuropsychological adj (assess* or evaluat* or test* or exam* or battery)).ti,ab 119. Self report/ 120. self-assessment/ or diagnostic self evaluation/ 121. Mass Screening/ 122. early diagnosis/ 123. or/111-122 124. 74 or 123 125. 110 and 124 126. 74 or 123 127. 84 and 106 and 126 128. 74 and 106 129. 125 or 127 or 128 130. exp Animals/ not Humans.sh. 131. 129 not 130	
TOTAL before de-duplication		Nov 2012: 40993 May 2014: 6818 **TOTAL: 47812**
TOTAL after de-dupe		**24310**

Appendix 3. Information for extraction to proforma

Bibliographic details of primary paper: Author, title of study, year
Details of index test

- Language of test
- Was any translation of MMSE validated? (yes/no)
- MMSE Diagnostic Threshold
- Was the threshold pre-specified? (yes/no)
- Who administered the MMSE?
- Was index test conducted without knowledge of reference standard results?
- Could the conduct or interpretation of the index test have introduced bias?
- Notes on conduct of index test

Reference Standard

- Target condition
- What was the prevalence of dementia in the sample population?
- Who administered the reference standard?
- Reference Standard
- Was any attempt made to subtype dementia categories?
- Was reference standard interpreted without knowledge of index test results?

Study population

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- Country of study
- Number of participants
- Number of participants in analysis
- Patient sampling
- Consecutive/random sampling (yes/no)
- Did the study avoid inappropriate exclusions? (yes/no)
- Could the selection process have introduced bias? (yes/no)
- Comments on sampling, inclusions and exclusions
- What is the patient population?
    - Unselected community
    - Community with possible memory problem
    - Unselected primary care
    - Primary care with possible memory problem
- Age
- Gender (% female participants)
- Years of education
- Social class
- Comorbidity

Patient flow and timing

- What was the interval between index test and reference standard?
- Did all participants receive a reference standard?
- Did all participants receive the same reference standard?
- Notes of reference standard procedure.
- Were all participants included in the analysis?
- Were those not included in the analysis fully accounted for?
- Notes on patient flow and timing
- Other characteristics (e.g. ApoE status)
- Attrition and missing data

Appendix 4. Assessment of methodological quality QUADAS-2

Domain	Patient selection	Index test	Reference standard	Flow and timing
Description	Describe methods of patient selection: Describe included patients (prior testing, presentation, intended use of index test and setting)	Describe the index test and how it was conducted and interpreted	Describe the reference standard and how it was conducted and interpreted	Describe any patients who did not receive the index test(s) or reference standard or who were excluded from the 2 x 2 table (refer to flow diagram): Describe the time interval and any interventions between index test(s) and reference standard
Signalling questions (yes/no/unclear)	Was a consecutive or random sample of patients enrolled?	Were the index test results interpreted without knowledge of the results	Is the reference standard likely to correctly classify the target condition?	Was there an appropriate interval between index test(s) and reference

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(*Continued*)

		of the reference standard?		standard?
	Was a case-control design avoided?	If a threshold was used, was it pre-specified?	Were the reference standard results interpreted without knowledge of the results of the index test?	Did all patients receive a reference standard?
	Did the study avoid inappropriate exclusions?			Did all patients receive the same reference standard?
				Were all patients included in the analysis?
Risk of bias: (High/low/ unclear)	Could the selection of patients have introduced bias?	Could the conduct or interpretation of the index test have introduced bias?	Could the reference standard, its conduct, or its interpretation have introduced bias?	Could the patient flow have introduced bias?
Concerns regarding applicability: (High/low/ unclear)	Are there concerns that the included patients do not match the review question?	Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Are there concerns that the target condition as defined by the reference standard does not match the review question?	-

Appendix 5. Anchoring statements for quality assessment of Mini Mental State Examination (MMSE) diagnostic studies

We provide some core anchoring statements for quality assessment of diagnostic test accuracy reviews of the MMSE in dementia. These statements are designed for use with the QUADAS-2 tool and were derived during a two day, multidisciplinary focus group in 2010. If a QUADAS-2 signalling question for a specific domain is answered 'yes' then the risk of bias can be judged to be 'low'. If a question is answered 'no' this indicates a risk of potential bias. The focus group was tasked with judging the extent of the bias for each domain. During this process it became clear that certain issues were key to assessing quality, whilst others were important to record but less important for assessing overall quality. To assist, we describe a 'weighting' system. Where an item is weighted 'high risk' then that section of the QUADAS-2 results table is judged to have a high potential for bias if a signalling question is answered 'no'. For example in dementia diagnostic test accuracy studies, ensuring that clinicians performing dementia assessment are blinded to results of index test is fundamental. If this blinding was not present then the item on reference standard should be scored 'high risk of bias', regardless of the other contributory elements. Where an item is weighted 'low risk' then it is judged to have a low potential for bias if a signalling question for that section of the QUADAS-2 results table is answered 'no'. Overall bias will be judged on whether other signalling questions (with a high risk of bias) for the same domain are also answered 'no'.

In assessing individual items, the score of unclear should only be given if there is genuine uncertainty. In these situations review authors will contact the relevant study teams for additional information.

Anchoring statements to assist with assessment for risk of bias

Domain 1: Patient selection

Risk of bias: could the selection of patients have introduced bias? (high/low/unclear)

Was a consecutive or random sample of patients enrolled?

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Where sampling is used, the methods least likely to cause bias are consecutive sampling or random sampling, which should be stated, described or both. Non-random sampling or sampling based on volunteers is more likely to be at high risk of bias.
Weighting: high risk of bias
Was a case-control design avoided?
Case-control study designs have a high risk of bias, but sometimes they are the only studies available especially if the index test is expensive or invasive. Nested case-control designs (systematically selected from a defined population cohort) are less prone to bias but they will still narrow the spectrum of patients that receive the index test. Study designs (both cohort and case-control) that may also increase bias are those designs where the study team deliberately increases or decreases the proportion of subjects with the target condition, for example a population study may be enriched with extra dementia subjects from a secondary care setting.
Weighting: High risk of bias
Did the study avoid inappropriate exclusions?
The study will be automatically graded as unclear if exclusions are not detailed (pending contact with study authors). Where exclusions are detailed, the study will be graded as 'low risk' if exclusions are felt to be appropriate by the review authors. Certain exclusions common to many studies of dementia are: medical instability; terminal disease; alcohol/substance misuse; concomitant psychiatric diagnosis; other neurodegenerative condition. However if 'difficult to diagnose' groups are excluded this may introduce bias, so exclusion criteria must be justified. For a community sample we would expect relatively few exclusions. Post hoc exclusions will be labelled 'high risk' of bias.
Weighting: high risk of bias
Applicability: are there concerns that the included patients do not match the review question? (high/low/unclear)
The included patients should match the intended population as described in the review question. If not already specified in the review inclusion criteria, setting will be particularly important - the review authors should consider population in terms of symptoms; pre-testing; potential disease prevalence. Studies that use very selected subjects or subgroups will be classified as low applicability, unless they are intended to represent a defined target population, for example, people with memory problems referred to a specialist and investigated by lumbar puncture.

Domain 2: Index Test

Risk of bias: could the conduct or interpretation of the MMSE have introduced bias? (high/low/unclear)
Were the MMSE results interpreted without knowledge of the reference standard?
Terms such as 'blinded' or 'independently and without knowledge of' are sufficient and full details of the blinding procedure are not required. This item may be scored as 'low risk' if explicitly described or if there is a clear temporal pattern to the order of testing that precludes the need for formal blinding i.e. all MMSE assessments were performed before the dementia assessment. As most neuropsychological tests are administered by a third party, knowledge of dementia diagnosis may influence their ratings; tests that are self-administered, for example using a computerised version, may have less risk of bias.
Weighting: High risk
Were the MMSE cut points pre-specified?
For neuropsychological scales there is usually a cut point above which subjects are classified as 'test positive'; this may also be referred to as threshold; clinical cut-off or dichotomisation point. Different cut points are used in different populations. A study is classified at higher risk of bias if the authors define the optimal cut-off post hoc based on their own study data. Certain papers may use an alternative methodology for analysis that does not use thresholds, and these papers should be classified as not applicable.
Weighting: low risk
Were sufficient data on MMSE application given for the test to be repeated in an independent study?
Particular points of interest include method of administration (for example self-completed questionnaire versus direct questioning interview); nature of informant; language of assessment. If a novel form of the index test is used, for example a translated questionnaire, details of the scale should be included and a reference given to an appropriate descriptive text, and there should be evidence of validation.
Weighting: low risk
Applicability: are there concerns that the MMSE, its conduct, or interpretation differ from the review question? (high/low/unclear)
Variations in the length, structure, language and administration of the index test may all affect applicability if they vary from those specified in the review question.

Domain 3: Reference Standard

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Risk of bias: could the reference standard, its conduct, or its interpretation have introduced bias? (high/low/unclear)

Is the reference standard likely to correctly classify the target condition?

Commonly used international criteria to assist with clinical diagnosis of dementia include those detailed in DSM-IV and ICD-10. Criteria specific to dementia subtypes include but are not limited to NINCDS-ADRDA criteria for Alzheimer's dementia; McKeith criteria for Lewy Body dementia; Lund criteria for frontotemporal dementias; and the NINDS-AIREN criteria for vascular dementia. Where the criteria used for assessment is not familiar to the review authors and the Cochrane Dementia and Cognitive Improvement group this item should be classified as 'high risk of bias'.

Weighting: high risk

Were the reference standard results interpreted without knowledge of the results of the MMSE?

Terms such as 'blinded' or 'independent' are sufficient, and full details of the blinding procedure are not required. This may be scored as 'low risk' if explicitly described or if there is a clear temporal pattern to order of testing i.e. all dementia assessments performed before [neuropsychological test] testing.

Informant rating scales and direct cognitive tests present certain problems. It is accepted that informant interview and cognitive testing is a usual component of clinical assessment for dementia, however specific use of the scale under review in the clinical dementia assessment should be scored as high risk of bias.

Weighting: high risk

Was sufficient information on the method of dementia assessment given for the assessment to be repeated in an independent study?

Particular points of interest for dementia assessment include the training/expertise of the assessor; and whether additional information was available to inform the diagnosis (e.g. neuroimaging; other neuropsychological test results), and whether this was available for all participants.

Weighting: variable risk, but high risk if method of dementia assessment not described

Applicability: are there concerns that the target condition as defined by the reference standard does not match the review question? (high/low/unclear)

There is the possibility that some methods of dementia assessment, although valid, may diagnose a far smaller or larger proportion of subjects with disease than in usual clinical practice. In this instance the item should be rated poor applicability.

Domain 4: Patient flow and timing (n.b. refer to, or construct, a flow diagram)

Risk of bias: could the patient flow have introduced bias? (high/low/unclear)

Was there an appropriate interval between the MMSE and reference standard?

For a cross-sectional study design, there is potential for the subject to change between assessments, however dementia is a slowly progressive disease, which is not reversible. The ideal scenario would be a same day assessment, but longer periods of time (for example, several weeks or months; and up to six months) are unlikely to lead to a high risk of bias.

Weighting: low risk

Did all subjects receive the same reference standard?

There may be scenarios where subjects who score 'test positive' on the index test have a more detailed assessment for the target condition. Where dementia assessment (or reference standard) differs between subjects this should be classified as high risk of bias.

Weighting: high risk

Were all subjects included in the final analysis?

Drop outs (and missing data) should be accounted for. Attrition that is higher than expected (compared to other similar studies) should be treated as a high risk of bias.

Weighting: high risk

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WHAT'S NEW

Last assessed as up-to-date: 31 May 2014.

Date	Event	Description
11 April 2016	Amended	Error in plain language summary corrected

CONTRIBUTIONS OF AUTHORS

Sam Creavin wrote and revised the protocol, screened citations, reviewed full text articles, extracted data, assessed quality of studies, performed meta-analysis and wrote the manuscript.

Susanna Wisniewski helped draft the protocol, screened citations, reviewed full text articles, extracted data, assessed quality of studies and helped to draft the manuscript.

Anna H Noel-Storr helped draft the protocol, screened citations, reviewed full text articles, extracted data and assessed quality of studies and helped to draft the manuscript.

Sarah Cullum helped draft the protocol, screened citations, reviewed full text articles and helped to draft the manuscript.

DECLARATIONS OF INTEREST

The authors declare no conflict of interest.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- National Institute of Health Research, UK.

Sam Creavin is an NIHR Academic Clinical Fellow.

- NIHR, UK.

This review was supported by the National Institute for Health Research, via a Cochrane Programme Grant to the Cochrane Dementia and Cognitive Improvement group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Data extraction

We planned to extract data on study characteristics and quality to a study-specific pro forma. However, we finally entered the data directly into RevMan because the number of studies that were eligible for inclusion was so large that we wanted to avoid any possibility of introducing errors in transcribing data from one file or format to another (RevMan 2014). At least two senior authors worked together in real time to perform data entry and check the transcription to avoid human error.

Analysis

We anticipated that the target condition would comprise two categories: (1) dementia (all-cause) and (2) dementia subtypes (Alzheimer's, vascular, Lewy body, frontotemporal), but our included studies only reported the all-cause dementia outcome, so we only performed meta-analysis with this as the target condition.

Sensitivity analyses

We planned to perform sensitivity analysis to determine the effect of excluding studies that we deemed to be at high risk of bias. However, as studies were generally at low risk of bias - no study had more than two of four QUADAS-2 items assessed as having a high risk of bias - we did not do this as we did not pre-specify a point at which we would deem a study to be at overall 'high risk of bias'.

Heterogeneity

We did not investigate heterogeneity in test accuracy by education because this was poorly reported. We could not examine heterogeneity by mean MMSE score because the models were unstable.

INDEX TERMS

Medical Subject Headings (MeSH)

Alzheimer Disease [diagnosis]; Community Health Services; Dementia [*diagnosis]; Dementia, Vascular [diagnosis]; Lewy Body Disease [diagnosis]; Mental Status Schedule; Neuropsychological Tests [*standards]; Primary Health Care; Randomized Controlled Trials as Topic

MeSH check words

Aged; Humans

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