

BMJ Open Is traditional Chinese medicine recommended in Western medicine clinical practice guidelines in China? A systematic analysis

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ABSTRACT

Background: Evidence-based medicine promotes and relies on the use of evidence in developing clinical practice guidelines (CPGs). The Chinese healthcare system includes both traditional Chinese medicine (TCM) and Western medicine, which are expected to be equally reflected in Chinese CPGs.

Objective: To evaluate the inclusion of TCM-related information in Western medicine CPGs developed in China and the adoption of high level evidence.

Methods: All CPGs were identified from the China Guideline Clearinghouse (CGC), which is the main Chinese organisation maintaining the guidelines issued by the Ministry of Health of China, the Chinese Medical Association and the Chinese Medical Doctors' Association.

TCM-related contents were extracted from all the CPGs identified. Extracted information comprised the institution issuing the guideline, date of issue, disease, recommendations relating to TCM, evidence level of the recommended content and references supporting the recommendations.

Results: A total of 604 CPGs were identified, only a small number of which (74/604; 12%) recommended TCM therapy and only five guidelines (7%) had applied evidence grading. The 74 CPGs involved 13 disease systems according to the International Classification of Diseases 10th edition. TCM was mainly recommended in the treatment part of the guidelines (73/74, 99%), and more than half of the recommendations (43/74, 58%) were related to Chinese herbal medicine (single herbs or herbal treatment based on syndrome differentiation).

Conclusions: Few Chinese Western medicine CPGs recommend TCM therapies and very few provide evidence grading for the TCM recommendation. We suggest that future guideline development should be based on systematic searches for evidence to support CPG recommendations and involve a multidisciplinary approach including TCM expertise.

INTRODUCTION

Clinical practice guidelines (CPGs) are systematically developed statements to assist clinicians and healthcare professionals to make appropriate clinical decisions in

Strengths and limitations of this study

- This is the first comprehensive analysis of traditional Chinese medicine (TCM) therapies included in Western medicine clinical practice guidelines in China.
- The implications for future updating and development of Western medicine clinical practice guidelines involving TCM are highlighted.
- There are limitations to this study as guidelines from other countries that recognise TCM were not included and a rigorous quality assessment of all Chinese clinical practice guidelines was not conducted.

specific circumstances. Previous guidelines, which were mainly based on informal expert consensus, were influenced by expert clinical experience, training and subjective judgement.^{1 2} With the development of evidence-based medicine (EBM), guidelines increasingly demand the use of evidence, applying the principles of EBM to the process of guideline development. The generation of guideline recommendations involves both content and methodology experts, and the process should be clearly defined and reproducible.³ The commonly used standard that underpins the development of evidence-based CPGs was initially developed by the Scottish Intercollegiate Guidelines Network (SIGN).⁴ Over the past decade clinical guidelines have increasingly become a familiar part of clinical practice,⁵ and over the last 5 years the rate of publication of new CPGs has increased rapidly in China.⁶

The China Guideline Clearinghouse (CGC) is the major resource for CPGs in China.⁷ It is jointly initiated and run by the Evidence-Based Medicine Specialty Committee under the Chinese Medical Doctors' Association and the Chinese



Medical Association journal board. CGC is an internet collection of CPGs published in Chinese medical journals and is used as a platform for clinicians and the public.

Complementary and alternative medicine (CAM) consists of a wide range of healthcare practices, products and therapies.^{8 9} Traditional Chinese medicine (TCM) is usually considered to be part of CAM in the West and involves a broad range of medicine practices sharing common concepts that have been developed in China. TCM is based on a tradition that has evolved over more than 3000 years and includes various forms of herbal medicine, acupuncture, massage (*Tuina*), exercise (*Qigong*) and dietary therapy.¹⁰

Western medicine and TCM are parallel and equally important healthcare systems in China, and the Chinese government has encouraged the integration of Western medicine and TCM. Currently, the use of Chinese patent herbal medicine is widespread and reimbursed by the government insurance system. Reports have suggested that 60% of Chinese patent herbal medicines are prescribed by medical doctors in Western medicine hospitals.¹¹ A large-scale survey organised by Beijing Municipal Administration of Traditional Chinese Medicine and Beijing Association of Chinese Medicine found that 40% of prescriptions of patent herbal medicine by Western medicine doctors was inappropriate due to lack of TCM knowledge.¹¹

This study aims to assess the status of TCM recommended as an intervention in Western medicine CPGs in China and the use of evidence that underpins these recommendations. Our purpose in doing this is to provide an appropriate evidence-based strategy for the development of Western medicine CPGs that include TCM.

METHODS

Inclusion criteria

Guidelines approved and issued by the Ministry of Health of China, the Chinese Medical Association and the Chinese Medical Doctors' Association were all included in the initial review. Subsequently, all CPGs containing TCM were included in the study. Older versions of the guidelines with existing updates were excluded.

Data sources

CPGs were identified from the CGC from 2004 (when the first guideline was issued in China) to 14 January 2013. A supplementary search of CPGs was conducted up to 30 August 2014 in the China National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP) and Wan Fang database. The search strategy and search terms used were as follows: ('clinical' (*linchuang*) or 'prevention' or 'practice' or 'treat' or 'operation' or 'pharmacy' or 'drug' or 'treatment') and ('guideline' or 'standard' or 'proposal' or

'recommendation' or 'consensus' or 'criterion') and ('Ministry of Health of the People's Republic of China' or 'Chinese Medical Association' or 'Chinese Medical Doctor Association').

Data extraction

Any mention of the term 'TCM' in the included guidelines was regarded as having TCM-related content. Three authors (JR, JS and WYL) extracted the following information relating to TCM: the organisation issuing the guideline, date of issue, disease, location in guidelines of TCM content, recommended TCM content, evidence level of the recommendation and references supporting the recommendations. Data were extracted onto a Microsoft Excel 2010 spreadsheet for data manipulation.

Data analysis

Frequency data were generated for descriptive statistical analysis using Microsoft Excel 2010.

RESULTS

A total of 604 CPGs were identified and issued by three organisations between 2004 and 2014, and 74 guidelines (12%) mentioned TCM (table 1 and online supplementary file).¹²⁻⁸⁵ Over the past 10 years there was an overall increase in the number of CPGs, but there was no significant increase in those with TCM content (figure 1). The number of published guidelines including TCM content reached its maximum between 2010 and 2014, peaking at 16 new guidelines in 2013 (complete data for 2014 are not currently available). The first guideline to recommend TCM was published in 2005 (figure 1).

Subsequent analysis of the 604 CPGs according to the International Classification of Diseases, 10th edition (ICD-10) identified 21 disease systems. Of the 74 guidelines with TCM content, 58 different diseases were identified and these involved 13 specific disease systems (figure 2).

Table 1 Distribution of Western medicine clinical practice guidelines among three organisations

Name of organisation	No of CPGs	No of CPGs recommending TCM (%)
Chinese Medical Association	526	61* (12%)
Chinese Medical Doctors Association	47	4* (9%)
Ministry of Public Health	35	9* (26%)
Total	604	74 (12%)

*This excludes those jointly issued by multiple agencies and old version guidelines with existing updated ones. CPG, clinical practice guideline; TCM, traditional Chinese medicine.

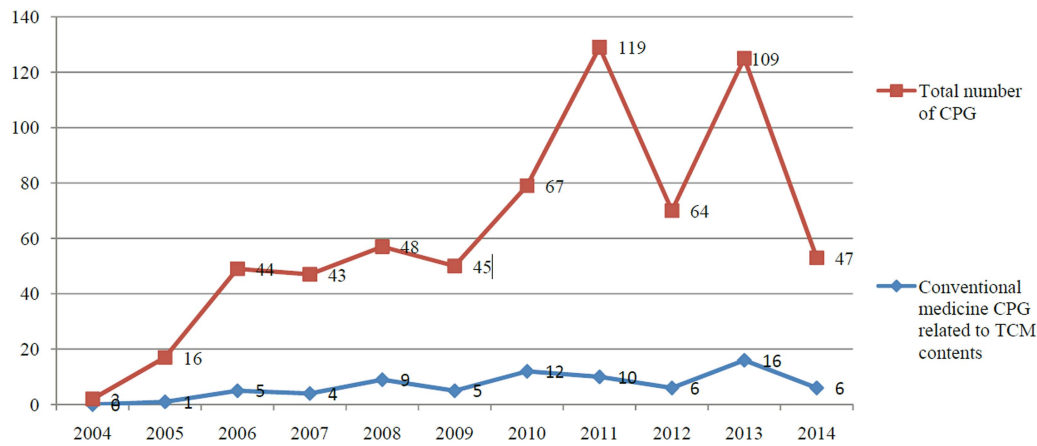


Figure 1 Number of clinical practice guidelines approved in China. The figure shows the trend among Western medicine clinical practice guidelines (CPGs) with respect to traditional Chinese medicine (TCM) content in the period 2004–2014.

In the 74 CPGs with TCM content, one mentioned TCM in the introduction (1%), one in the diagnosis of syndrome differentiation (1%), but most of the guidelines mentioned TCM in the treatment recommendation section (73, 99%). In addition, TCM recommendations were described under prevention (three guidelines, occupying 4% of the total guideline number) and two under rehabilitation (3%). Five guidelines mentioned TCM in more than one section of the guideline.

Among the 74 CPGs with TCM content, 43 guidelines (58%) recommended a Chinese herbal treatment (including single herbs or multiple herbs based on syndrome differentiation) and, among them, 25 guidelines (34%) recommended Chinese proprietary medicine or herbal preparations produced by a hospital pharmacy and not necessarily approved by the State Food and Drug Administration. In addition, 14 guidelines (19%) recommended acupuncture, one guideline recommended acupuncture point injection (1%) and 14 guidelines recommended two or more TCM therapies (table 2).

Of the 74 CPGs with TCM content, only five guidelines (7%) provided evidence grading for the TCM recommendations.^{50 51 53 54 56} Three guidelines reported level I evidence related to TCM,^{50 53 54} four guidelines reported level II evidence related to acupuncture and herbal extracts^{41 53 54 58} and three guidelines reported level III evidence related to Chinese patent medicine and massage.^{53 54 64} All these guidelines specified the herbal compositions (table 3).

Two of the 74 CPGs with TCM content mentioned that “due to the limited literature involving TCM studies and small sample sizes, more evidence was needed before making firm recommendations” and “further high-quality studies should be conducted to confirm the effects of TCM treatments”.^{51 53} Three guidelines did not provide further comments after recommending TCM treatments.^{50 52 58} The other 69 guidelines did not provide the evidence level for their recommendation for TCM treatments, but only listed a general statement—for example, “TCM treatment: apply TCM treatment

methods such as herbal medicines, acupuncture, acupuncture injection, and *Tuina*, which should be based on syndrome differentiation”.²⁰

Of the 74 CPGs with TCM content, only 11 mentioned appropriate references to TCM such as systematic reviews (n=3),^{51 53 71} randomised controlled trials (n=6),^{17 50 51 54 58 71} non-randomised controlled trials (n=2),^{54 58} case series (n=4)^{24 51 54 71} or other (n=1) (historical TCM classical texts).⁸²

DISCUSSION

Few Western medicine CPGs in China recommended TCM, and very few guidelines applied an evidence-based approach in the recommendations. The majority of the TCM therapies (58%) recommended were Chinese herbal medicine, and about 59% of the recommendations were for chronic diseases such as chronic hepatitis B, bronchial asthma and type 2 diabetes mellitus. The TCM content of the 74 CPGs failed to provide adequate references to research published in international journals. In addition, the methodology regarding how the TCM recommendations were formulated was not transparent or evidence-based.

This study systematically assessed the status of TCM therapy recommended in 604 Western medicine CPGs issued by three state level organisations in China. To the best of our knowledge, this is the first comprehensive analysis detailing the inclusion of TCM content in Western medicine CPGs published in China. Recommendations for TCM in the current Chinese guidelines are not reflected by its popularity in practice. The findings of this study provide insights for the future development and updating of CPGs involving Western medicine and TCM in China.

This study has some limitations. First, the included guidelines were all identified from the China Guideline Clearinghouse and issued by the Ministry of Health, the Chinese Medical Association and the Chinese Medical Doctors' Association. These guidelines are easily

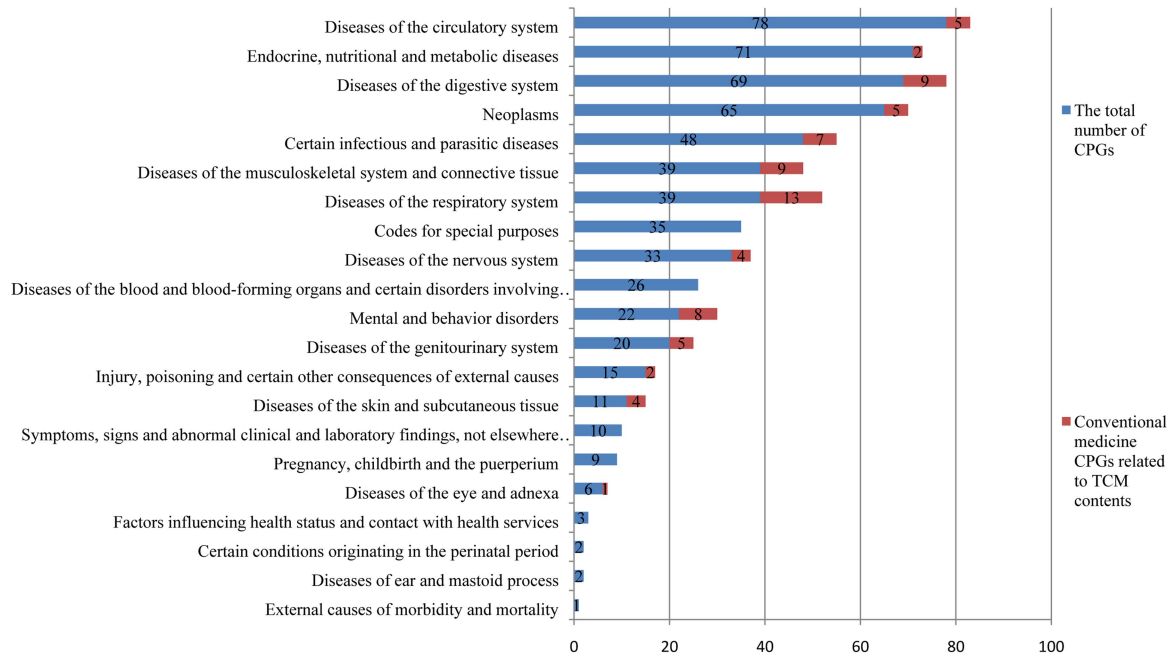


Figure 2 Categories of diseases involved in clinical practice guidelines in China. The figure shows the number of disease categories involved in the total number of clinical practice guidelines (CPGs) and Chinese Western medicine CPGs with related traditional Chinese medicine (TCM) content, respectively.

accessible and published centrally but may not be comprehensive as some guidelines may be issued by other relevant Chinese professional societies. Second, we did not include guidelines from other countries that recognise TCM (eg, the use of acupuncture for pain in the USA and Europe) so we are unable to comment about the specific evidence for TCM in treatment guidelines in other countries. Third, we only evaluated evidence grading in those CPGs that recommended TCM so we are not able to reach any conclusions about the CPGs that did not recommend TCM.

This study shows that Western medicine CPGs do not include adequate relevant research to support the guidelines' recommendations for TCM. It appears that trials and systematic reviews carried out in the West may not be included as evidence even though the research may be of good quality. One article published in 2014 identified 13 guidelines and 22 systematic reviews issued by East Asian countries on traditional medicine (including acupuncture, moxibustion, cupping, herbal medicine, TCM, manual therapy and *Tuina*) for low back pain.⁸⁷ This study suggested that the current CPGs do not fully reflect the evidence for traditional medicine interventions and concluded that, as relevant studies, systematic reviews and meta-analyses are conducted and the evidence increases, the current evidence on acupuncture, herbal medicine and manual therapy should be reconsidered in the process of developing or updating relevant CPGs. Similarly, in the UK, a recent study of NHS Western medical clinical guidelines issued by the National Institute for Health and Care Excellence

demonstrated a low proportion of CPGs mentioning at least one CAM.⁸⁸ Out of 279 UK clinical guidelines issued during 2006–2013, only 16% mentioned CAM, with acupuncture and natural herbal medicines being the most common. For acupuncture, six guidelines recommended its use, three stated that it could be considered but the evidence was weak, 18 could not recommend acupuncture based on the available evidence and six advised against the use of acupuncture. Thirty-six guidelines mentioned the use of various natural products including herbs. Interestingly, there were more guidelines mentioning acupuncture in the UK than there were in China over the same time period.⁸⁸

Our study shows that there is insufficient application of TCM research evidence in Western medicine guidelines in China. This may be because the guideline developers did not identify the relevant evidence when preparing the guidelines, but it is important to note that most of the guidelines did not have clear methodology for how they had been developed. One recent study reported that there were 2964 controlled clinical trials involving TCM in cancer treatment published in China between 1984 and 2011, and the number of such publications increases annually, but these data do not seem to have been used in guideline development.⁸⁹ For instance, Cao *et al*⁹⁰ identified 550 Chinese clinical studies on cupping therapy published between 1959 and 2008 but, again, these did not attract adequate attention in the field of guideline development. A large number of reviews on TCM have reported a high level of interest,⁹¹ but there is little or no reliable evidence with positive findings for

Table 2 Traditional Chinese medicine therapy recommended in Western medicine clinical practice guidelines

TCM therapy	No of CPGs	Diseases involved (no of guidelines if >1)
Chinese herbal medicine	43	Chronic hepatitis B (3), bronchial asthma (3), nasosinusitis (2), chronic obstructive pulmonary disease (2), type 2 diabetes mellitus (2), allergic rhinitis, avascular necrosis of the femoral head, common kidney disease in children, childhood diarrhoea, hepatolenticular degeneration, osteoporotic fracture, heart failure, colorectal cancer, influenza, difficult asthma, pelvic inflammatory disease, spleen injury, spleen retained, prostatitis, eczema, baby allergic disease, primary hepatic carcinoma, haemorrhoids, obesity, psoriasis, severe acute pancreatitis, spinal cord injury, colorectal cancer, drug-induced liver injury, limb atherosclerosis, inflammatory bowel disease, vasomotor rhinitis, acute pancreatitis, chronic constipation, influenza, hand-foot-and-mouth disease, optic neuritis, chronic venous disease
Chinese proprietary medicine* or traditional Chinese preparation†	25	Cerebrovascular disease (2), primary liver cancer (2), dementia and cognitive impairment (2), viral hepatitis, gastrointestinal disease, Behcet syndrome, adult onset Still's disease, rheumatoid arthritis, influenza, Malassezia-associated diseases, eczema, vascular cognitive impairment, bronchial asthma, type 2 diabetes mellitus, acute ischaemic stroke, psoriasis, management of menopause, nasosinusitis, influenza, hand-foot-and-mouth disease, acute paraquat poisoning, fatty liver disease
Acupuncture and/or moxibustion	14	Stroke (2), irritable bowel syndrome, childhood diarrhoea, prostatitis, fibromyalgia syndrome, haemorrhoids, adult insomnia, acute ischaemic stroke, migraine, management of menopause, chronic constipation, child autism, acne
Acupuncture point injection	1	Childhood diarrhoea

*Chinese patent medicine, Chinese herbal preparation or Chinese herb extracts.

†The forms were unspecified.

As one guideline may recommend more than one kind of TCM therapy, the total number of guidelines involved is larger than 74.

CAM including TCM mainly due to the poor methodological quality of the original studies.⁹² Thus, whether there is adequate evidence to recommend TCM in guidelines included in this study is still not known, and this should be the focus of future research.

In spite of these caveats, it appears that (1) there is insufficient evidence to recommend TCM for some conditions and further research is required; (2) the evidence on the quality, safety and efficacy of traditional medicine does not meet the applicable standards for Western medicine;⁹³ and (3) Chinese guidelines are generally of poor quality and have mostly been developed through expert consensus and lack rigorous scientific methodology.⁹⁴

Based on the findings from our study, we make the following suggestions for the future development of Chinese clinical guidelines. First, all guidelines should be evidence-based so that the recommendations can be supported by research evidence. Adopting an evidence-based approach to the development of CPGs has become an international trend,⁴ and CPGs should be founded on the highest quality of scientific evidence available. In the Chinese context (reflecting the

popularity of TCM), considerable effort should be made to look at both Western medicine and TCM to reflect and support their clinical use. Second, many of the original Chinese studies are of poor quality, challenging their utility as evidence in China and abroad,⁹⁵ and there is an urgent need to improve the methodology and reporting of randomised controlled trials in China. Third, different stakeholders should be involved in the development of CPGs such as Western medical doctors, TCM practitioners, methodologists, information personnel, nurses and healthcare policy makers.⁹⁶

CONCLUSIONS

TCM is included in 12% of Western medicine guidelines in China. Few guidelines that recommend TCM provide references, and very few have applied evidence grading to support their recommendations. Future guideline development in China should be based on internationally recognised methodology with relevant stakeholders involved. We suggest systematic searching and synthesising of evidence, critical appraisal of evidence, and reporting the evidence with reference to the Grading of

Table 3 Recommendations based on evidence level for traditional Chinese medicine content in Western medicine clinical practice guidelines

Recommendation level	Guideline title	Treatment	Recommendation contents
Level I	Chinese guidelines on diagnosis and management for cognitive impairment and dementia	Chinese herbal preparation	Ginkgo leaf preparation has a mild effect in slowing down memory in older patients (grade A evidence). Does not stop or slow down the development from MCI to dementia (grade A evidence)
	Chinese guidelines on rehabilitation treatment for stroke (2011 full version)*	Traditional Chinese medicine	For stroke rehabilitation, traditional Chinese medicine therapies can be added to conventional rehabilitation therapy (grade A evidence)
	Guidelines on management for stroke rehabilitation (Simplify)†	Traditional Chinese medicine	In the rehabilitation process of stroke, traditional Chinese medical therapies can be included as part of conventional rehabilitation therapy (grade A evidence)
Level II	Chinese guidelines on prevention and treatment for acute ischaemic stroke (2010)	Acupuncture	Decision to choose acupuncture should take into account the patient's willingness to have acupuncture (level II recommendation, grade B evidence)
	Chinese guidelines on rehabilitation treatment for stroke (2011 full version)	Acupuncture	Acupuncture can speed up physical recovery and improve motor ability during the flaccid paralysis stage of stroke patients (level II recommendation, grade B evidence).
	Guidelines on the management for stroke rehabilitation (Simplify)	Acupuncture	Acupuncture may be used in bulbar paralysis patients (level II recommendation, grade B evidence). Acupuncture may be used for bulbar paralysis patients (level II recommendation, grade B evidence)
	Chinese guidelines on diagnosis and management for cognitive impairment and dementia (V): dementia therapy	Chinese herbal medicine and Chinese herbal preparation	Ginkgo leaf may improve the neuropsychic symptoms and slow down the disease progression of dementia (grade B evidence). Ginkgo leaf extract does not reduce the incidence of AD in elderly people with mild cognitive impairment (grade B evidence). <i>Salvia officinalis</i> extract is able to improve cognitive function in mild and moderate AD patients and relieve the symptoms of agitation (grade B evidence)
Level III	Chinese guidelines on prevention and treatment for acute ischemic stroke (2010)	Chinese patent medicine	Decision to use acupuncture (level II recommendation, Grade B evidence) should take patient's willingness into consideration, Chinese proprietary medicine (level III recommendation, grade C evidence)
	Chinese guidelines of rehabilitation treatment for stroke (2011 full version)	Massage	Recommendation of massage for patients with severe limb spasm to relieve fatigue and muscular tension (level III recommendation, grade C evidence)
	Chinese guidelines on rehabilitation treatment for stroke (2011 full version)	Massage	Recommendation of massage for patients with severe limb spasm to relieve fatigue and muscular tension (level III recommendation, grade C evidence)

Quality evidence based on GRADE: A, high quality; B, moderate quality; C, low quality; D, very low quality.

Quality level based on GRADE:

1. High: we are very confident that the true effect lies close to that of the estimate of the effect.
2. Moderate: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect but there is a possibility that it is substantially different.
3. Low: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
4. Very low: we have very little confidence in the effect estimate; the effect is likely to be substantially different from the estimate of effect.

*Although the two articles have partially similar content, we regarded them as different guidelines because of different form and part of the content.

†If level of evidence involved did not identify a specific standard, it was assessed based on GRADE standards.⁸⁶

AD, Alzheimer's disease; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; MCI, mild cognitive impairment.

Recommendations, Assessment, Development and Evaluation (GRADE)⁹⁷ using the Appraisal of Guidelines for Research and Evaluation (AGREE) format (<http://www.agreecollaboration.org>).

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Contributors J-PL and JR conceived and designed the study. JR, JS and WYL performed the literature search, study selection, data extraction as well as data analyses. JR and XL drafted the paper. J-PL, XL, MH, G-YY, NR and GL provided methodological perspectives and revised the manuscript.

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