Effectiveness of Montessori-based activities on agitation among Asian patients with dementia
A systematic review and meta-analysis

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Abstract
Objectives: Montessori based activity are supposed to be an effective nonpharmacological intervention in the treatment of agitation in western countries. However, most studies conducted to evaluate the effectiveness of Montessori based activities on agitation in Asian patients were small sample size, as well as inconsistent outcomes, which may limit the reliability of the conclusions. The present pooled analysis, hence, was conducted to evaluate the effectiveness of the activity on agitation related with dementia in Asian patients with dementia.

Design: Prospective randomized clinical studies were included, of which available data was extracted. Outcomes of physical aggressive behaviors, physical nonaggressive behaviors, and verbal aggressive behaviors were pooled for the analysis by weighted mean differences.

Data sources: Medline, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), WanFang, and China Science and Technology Journal Database (VIP)

Eligibility criteria: Prospective, randomized, controlled clinical studies, conducted to evaluate the effectiveness of the activity on agitation related with dementia in Asian patients with dementia.

Data extraction and synthesis: Available data including baseline characteristics and interested outcomes from the included literature were extracted independently by 2 investigators. Measuring scales including CMAI and NOSIE were adopted for the efficacy comparison between Montessori based activity and standard activity. Weighted mean difference was used for the pooled analysis.

Results: A total of 460 participants were included in the present meta-analysis. The pooled mean difference agitation for Montessori based activity was –3.86 (95% CI: –7.38 to –0.34, \( P = 0.03 \)) comparing to standard activity. The pooled mean differences for physical aggressive behaviors, physical nonaggressive behaviors, and verbal aggressive behaviors in Montessori based activity group were –0.82 (95% CI: –1.10 to –0.55; \( P < 0.00001 \)), –0.81 (95% CI: –1.68 to 0.55; \( P = 0.07 \)), and 0.38 (95% CI: –0.92 to 1.68; \( P = 0.57 \)).

Conclusions: Montessori based activities may reduce the frequency of agitation, especially in physical aggressive behaviors comparing to standard activities in Asian patients with dementia. However, the effectiveness of Montessori based activities on reduction of subcategorized agitated behaviors including physical nonaggressive behaviors, and verbal aggressive behaviors may not be reliable as physical aggressive behaviors.

Abbreviations: CDR = Clinical Dementia Rating; CMAI = Cohen-Mansfield Agitation Inventory; CNKI = China National Knowledge Infrastructure; GDS = Global Deterioration Scale; MD = Mean Difference; MMSE = Mini-Mental State Examination; NICE = National Institute for Health and Care Excellence; NOSIE = Nurses’ Observation Scale for Inpatient Evaluation; NR = Not Reported; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses; SP = Standard Procedure; WHO = World Health Organization.

Keywords: agitation, Asian, dementia, meta-analysis, Montessori-based activities

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1. Introduction

Dementia, an irreversible chronic disease, is defined as a decline of cognitive capacity, which harm normal life, and usually presented as behavioral and psychological symptoms.[1] According to the public reports from World Health Organization (WHO), there are approximately 55 million people who have dementia, with more than 60% living in developing countries.[2] Because of the increasing proportion of older people population around the world, this number is expected to rise to 78 million in 2030 and 139 million in 2050. Dementia results from various diseases and injuries, which affect brain primarily or subsequently, and lead to physical, psychological, and social impacts, not only for patients with dementia themselves, but also for their families and society.[3] Agitation is one of the major persistent and distressing behavioral symptoms, affecting approximately half of all people with dementia.[4] Currently, few treatment strategies are supposed available to cure dementia related agitation. Antidementia medications and disease-relieving treatment developed have limited efficacy and are primarily labeled for Alzheimer disease to date, though numerous new treatments are being investigated in various stages of clinical trials.[5]

The Montessori based activity is an individual-centered, non-pharmacological intervention, which was initially designed and performed to improve the cognitive, sensorial, and social skills for children.[6] Because of the analogical behavioral and psychological symptoms between children and old patients with dementia, Montessori based activity has been adopted as candidate in clinical practice as one of nonpharmacological interventions for individuals with agitation by dementia.[7,8] There are 3 dominant elements, including a prepared environment, activity materials, and a facilitator during the administration of Montessori-based activity, which is aiming to encouraging patients to practice their existing abilities in prepared environment. Owning to the choice of teaching aids, the intrinsic motivation and interest are stimulated, which may contribute to the improvement of agitation symptoms. Based on that, dementia patients may exercise their thinking skills and rebuild self-esteem by the guidance and encouragement during the procedure.[9]

In recent decades, there are several studies with limited sample size conducted to investigate the effectiveness of the Montessori-based activity on the agitation. Yuen and his colleagues have sponsored a prospective study, in which 46 long-term care home residents with dementia were randomly enrolled to receive Montessori based activity (n = 23) or structured social activities as control (n = 23). Results of the study supported the potential role of the Montessori based activity as a safe and efficacious therapeutic intervention for relieving agitation in home residents with dementia, relevant to Hong Kong culture.[10] However, that study investigated the effect of the Montessori-based activity by only measuring the change in frequency and disruptiveness of agitation, rather than improvement over residents’ emotional expression and level of participation, which may lead to the lacking of mood and engagement assessment during the procedure. However in another relevant study, Montessori based activity was not proven effective on problem behaviors diminished in severe dementia patients.[5] The inconsistent outcomes on agitation may lead to confusing understanding of the efficacy of Montessori-based activity in dementia patients. Moreover, the majority of studies enrolled patients with small sample size (<100 patients), which may limit the reliability of the conclusions. Hence, the present systematic review and meta-analysis was conducted to evaluate the effectiveness of the Montessori based activity on the agitation in Asian patients with dementia.

2. Methods

2.1. Literature search

The studies screened in the present systematic review and meta-analysis were identified via databases, including Medline, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), WanFang, and China Science and Technology Journal Database (VIP). The deadline of the screening was up to December 31st 2021 restricting them to human subjects and clinical trials. The Mesh terms adopted in the present study were “Montessori,” “Dementia,” and their synonyms. The literature review was confined to prospective clinical trials, which were published in Chinese or English. However, meeting abstracts were not included because of potential publication bias induced by incomplete reporting data. The present meta-analysis was developed in compliance with the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions, which was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. All the included articles meeting the following prespecified PICOS criteria are considered eligible and included: P: patients with dementia; I: treated with Montessori based activity; C: treated with standard activities or observation; O: Efficacy evaluated with reliable scales including Cohen-Mansfield Agitation Inventory (CMAI) or Nurses’ Observation Scale for Inpatient Evaluation (NOSIE); S: randomized controlled trials or cohort studies.

2.2. Inclusion and exclusion criteria

Inclusion criteria used in the present study were presented as below: (1) Prospective, randomized, controlled studies. (2) Patients enrolled in the studies should be diagnosed as dementia, in accordance with the clinical criteria of Global Deterioration Scale (GDS), Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases or Mental State Examination (MMSE), or Clinical Dementia Rating (CDR). (3) Patients received Montessori based activities or standard activities to relieve dementia. (4) Efficacy of the treatments on dementia was evaluated with reliable scales including Cohen-Mansfield Agitation Inventory (CMAI) or Nurses’ Observation Scale for Inpatient Evaluation (NOSIE). (5) Sample size larger than twenty patients in a study. Accordingly, the following exclusion criteria were adopted: (1) Repeated reported studies. (2) The language was not in Chinese or English.

2.3. Data extraction

Available data including baseline characteristics and interested outcomes from the included literature were extracted independently by 2 investigators (Xu LY and Zhang ZH). Any controversies were resolved by the consultation from a third researcher (Xu XX). Essential characteristics extracted from the eligible studies were listed as below: first author’s names, publication year, regions, degree of dementia, sample size, age, interventions in the 2 groups, outcomes, and the measure scales. Measuring outcomes in the present meta-analysis included Chinese version of Cohen-Mansfield Agitation Inventory (CMAI) assessing agitated behaviors and their frequencies.[10] or Nurses’ Observation Scale for Inpatient Evaluation (NOSIE).[11] The CMAI scale consisted of 21 items agitated behaviors, which were categorized into physical aggressive behaviors, physical nonaggressive behaviors, verbal aggressive behaviors, and verbal nonaggressive behaviors. All behaviors were evaluated in the past 2 weeks, which were rated on a 7-point frequency scale. However, NOSIE scale was evaluated with 6 segments including depression, agitation, retardation, social interest, social function, and individual tidiness.[11] All segments were specified into 30 items, and rated on a 4-point scale. Higher scores in the CAMI and NOSIE scales suggested higher level of agitation in terms of frequency.
2.4. Quality assessment of included studies

Quality assessment of the included studies was performed with the criteria of Cochrane Collaboration’s tool for assessing risk of bias of randomized controlled trials by the 2 reviewers (Xu LY and Zhang ZH). The following items including random sequence generation, allocation concealment, binding of outcome assessments, binding of participants and personnel, incomplete outcome data, selective reporting and other bias were adopted for the final assessment, results of which were presented with “risk of bias graph” and “risk of bias summary.”

2.5. Statistical analysis

All data screened and included in the pooled analysis were continuous variable, which were analyzed with software RevMan, version 5.3. The difference between the Montessori group and the standard group were compared directly. Weighted mean difference was used for the comparisons among the studies with same measuring scale. However, standard mean difference was adopted for the comparisons among different scales. In addition, heterogeneity consistency of the included studies was assessed with the software RevMan, version 5.3. If values of 0 to 50%, as well as a \( P \) >0.05 were interpreted as low heterogeneity, 50% to 100% with \( P \) ≤0.05 as presenting high heterogeneity among studies. Fixed effects model or random effects one was applied for the analysis of data with heterogeneous or not. A \( P \)-value <0.05 was considered statistically significant. Potential publication bias was detected and presented with funnel plot by software RevMan 5.3.

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Figure 1. Study selection procedure with PRISMA flow diagram.
3. Results
A total of 589 potentially available literature were initially searched among databases including Medline, Embase, Cochrane Library, CNKI, WanFang, and VIP. Four hundred and nine articles were subsequently removed because of duplications. In total, 151 studies were further excluded with the property of controlled clinical studies. In accordance to the inclusion criteria, 24 studies were screened for potentially final assessment. After full text carefully reviewed, twenty studies had been conclusively eliminated because of retrospective studies (n = 9), small sample size <20 participants (n = 7), repeated reports (n = 2), and conferences abstracts (n = 2), respectively. Accordingly, a total of 4 prospective studies were considered eligible for the final analysis. A flow diagram which detailed the screening of included studies was presented in Figure 1.

As a result, a total of 460 participants were included in the meta-analysis of the present study, all of which received Montessori based activities or standard activities to relieve dementia. There are 3 groups in one of the included literature, which was classified into 2 comparisons according to the criteria in the present study.[12] Main characteristics of included studies are summarized in Table 1.

3.1. Quality assessment of the included studies
Quality assessment of included literature was performed within the criteria of Cochrane Collaboration’s tool for assessing risk of bias of RCTs. All studies reported the procedures of randomization in the article. Three studies were not blinded, leaving the other one remained unclear. However, it was improbable to influence the final comparisons according to the judgment of investigators. All the included studies reported the outcomes related to agitation with the scales in the present analysis. In addition, 4 studies satisfied the criteria of allocation concealment, with low risk of bias in attrition, reporting bias according to the 2 reviewers. Risk of bias summary and the bias graph were presented in Figure 2 and Figure 3.

3.2. Overall effectiveness of Montessori-based activities
Pooled analysis was classified into 2 subgroups in terms to the different measuring tools including CMAI and NOSIE. Results of heterogeneity evaluation among the included studies with test showed high risk of statistical heterogeneity ($I^2 = 55\%$ for CMAI, $P = 0.11$. $I^2 = 100\%$ for NOSIE, $P < 0.00001$). Random effects model was accordingly adopted for the overall analysis. The pooled mean difference (MD) for agitation was −3.86 (95% CI: -7.38 to -0.34; $P = 0.03$, Fig. 4), suggesting that Montessori based activities may contribute to the remission of dementia.

Subgroup analysis was conducted to assess the influence of measuring tool on the effectiveness. Evaluation with CMAI scale implied that Montessori based activities may decrease the frequency of dementia (MD = −3.47, 95% CI: −5.82 to −1.12; $P = 0.004$). However, the NOSIE scale failed to show the statistical difference (MD = −3.60, 95% CI: −9.12 to 1.93; $P = 0.20$), though a statistical trend emerged in the forest plot.

3.3. Behaviors specified comparisons
Specified behaviors including physical aggressive behaviors, physical nonaggressive behaviors, and verbal aggressive behaviors were pooled analyzed, respectively. The pooled mean differences for physical aggressive behaviors, physical nonaggressive behaviors, and verbal aggressive behaviors were −0.82 (95% CI: −1.10 to −0.55; $P < 0.00001$, Figure 5), −0.81 (95% CI: −1.68 to 0.55; $P = 0.07$, Fig. 6), and 0.38 (95% CI: −0.92 to 1.68; $P = 0.57$, Fig. 7).

3.4. Publication bias
Funnel plot with effectiveness did not reveal a significant publication bias according to Figure 8.

4. Discussion
In brief, results of the present study suggested that Montessori-based activities may reduce the frequency of agitation, especially in physical aggressive behaviors comparing to standard activities in Asian patients with dementia. However, the effect of Montessori-based activities on reduction of subcategorized agitated behaviors including physical nonaggressive behaviors, and verbal aggressive behaviors were not reliable as physical aggressive behaviors.

As one of the most destructive representations in dementia, symptoms of agitation received wide attention, as well as numerous strategies attempted to relieve that. In recent years, nonpharmacological sensory stimulation interventions including animal-assisted therapy, music intervention, as well as Montessori-based activities were recommended as candidate options in dementia patients who have comorbid agitation according to the guidelines of National Institute for Health and Care Excellence (NICE). Relevant prospective clinical studies have been performed to evaluate the efficacy of those nonpharmacological sensory stimulation interventions in real world, especially in Australia and East Asian. A randomized

| Study | Region          | Degree of dementia | Sample size | Age Mont. | Age Control | Interventions | Outcome | Scale |
|-------|-----------------|--------------------|-------------|-----------|-------------|---------------|---------|-------|
| Yuen 2019 | Nursing home    | Moderate Severe    | 23          | 86.17 ± 9.75 | 86.74 ± 6.09 | 45 min, 3 times a wk | SP      | Agitation | CMAI |
| Zhang 2019 | Hospital        | NR                 | 56          | 69.2 ± 1.3    | 70.3 ± 1.2    | 15–30min, 7 times a wk | SP      | Agitation | NOSIE |
| Lin 2009  | Nursing home    | Moderate Severe    | 94          | 80.9 ± 7.1    | 80.9 ± 7.8    | 15 min, 6 times a wk | SP      | Agitation | CMAI |
| Zhang 2020 | Hospital        | Mild Moderate      | 58          | 79.26 ± 6.15  | 79.31 ± 6.11  | 15–30min, 7 times a wk | SP      | Agitation | NOSIE |

Abbreviations: CMAI = Cohen-Mansfield Agitation Inventory, Mont = Montessori-based activities, NR = not reported, NOSIE = Nurses’ Observation Scale for Inpatient Evaluation, SP = standard procedure.

Table 1
Baseline characteristics of the studies included in the present study.
crossover trial, conducted in Australia, was performed to investigate the effectiveness of personalized, one-to-one interaction with Montessori-based activities on agitation and engagement in nursing home residents with dementia. Participants in the research were observed half an hour before, during, and after the Montessori-based activities. Physically nonaggressive behaviors were in inspected every minute, as well as the main type of engagement. Results of the study showed that the amount of time spend engaged was twice the time, as well as more positive affect and interest comparing to the group control, which suggested that even nonpersonalized social contact can be beneficial in settling agitated patients. In addition, results
Figure 3. Risk of bias graph: review authors’ judgments about each risk of bias item presented as percentages.

Figure 4. Forest plot of the mean difference for the effectiveness between Montessori based activities and standard activities with their confidence intervals.

Figure 5. Forest plot of the mean difference for physical aggressive behaviors between Montessori based activities and standard activities with their confidence intervals.

Figure 6. Forest plot of the mean difference for physical nonaggressive behaviors between Montessori based activities and standard activities with their confidence intervals.
of the research also revealed that catering activities to dementia patients’ needs and capabilities may lead to more positive interactions and are particularly suitable for patients who have lost fluency in the language spoken predominantly.[13] Another crossover trial was conducted in Asian patients, which was performed to study the efficacy of Montessori based activities and acupressure on improvement of agitated behaviors of residents with dementia.[12] Eligible dementia patients were randomized into 3 treatment groups: acupressure to presence to Montessori activities, Montessori activities to acupressure to presence and presence to Montessori activities to acupressure, respectively. All treatments were performed once a day, 6 days per week, up to a period with 4 weeks. As a result, Montessori-based-activities groups presented a significant decrease in agitated behaviors, not only aggressive behaviors, but also physically nonaggressive behaviors than the control group after receiving the intervention. In addition, Montessori based activities might be effective in elderly care that would be beneficial for patients with agitation, which was consistent to the former publications. However, in another randomized, controlled study conducted in China, the results suggested that agitation was not significantly relieved by Montessori-based-activities, though a trend was observed.[14] It was suggested that cognitive impairment was severe in patients with late-stage dementia, which might be hardly relieved by interventions. However, the present pooled analysis also enrolled patients with moderate to severe degree of dementia. Our results suggested that Montessori-based activities may reduce the frequency of agitation, especially in physical aggressive behaviors comparing to standard activities in patients with dementia, which was not significantly influenced by the damage degree of the dementia. We supposed that the duration of the intervention, as well as the evaluation scales used in the efficacy evaluation may contribute to the diverse outcomes. According to the results of subgroup analysis in the present study, statistical difference was observed in studies using CMAI scale rather than NOSIE scale, though an obvious trend presented. It should be pointed out that CMAI scale was designed specifically for the evaluation of agitation, which was classified into several respects.[15] However the NOSIE scale was a global evaluation of inpatient with psychopath, which included agitation as 1 part of the segments merely, results of that could not specify the variation of concrete behaviors such as physical aggressive behaviors, or verbal aggressive ones.[11] Based on that, we suggested that CMAI scale might be more appropriate in the assessment of agitation related to dementia. Duration of the intervention time by Montessori based activities may also lead to the distinguishing effectiveness of agitation. A long-term (6 months) intervention may comprehensively improve dementia-related behaviors, including eating difficulties, constructive engagement, and positive affect.[16] In addition, the improvement of dementia-related behaviors may also lead to the decreasing of medication use.[17] In the present research,
the intervention duration of the included studies for the behavior-specific analysis was less than 4 weeks, which may lead to a trend favors to Montessori-based activities, rather than statistical difference between the groups. Even so, the results of the meta-analysis suggested that Montessori-based activities might be beneficial and essential as treatment strategy in Asian dementia patients with agitation.

There were several limitations in the present meta-analysis. First of all, limited included studies, as well as small sample size in the enrolled studies, might lead to potential publication bias, which might finally limit the value of the conclusion in the present analysis. Besides, high heterogeneity of included studies during the comparison may result in another inaccuracy. Although random effects model was adopted for the pooled analysis, efficacy of the meta-analysis may decrease. Finally, interested data were not obtained from individual patients of included studies, which may limit the conclusion as a comprehensive analysis.

5. Conclusions
Montessori-based activities were widely used for the improvement of agitation in patients with dementia in western countries. However, the clinical application of the strategy has not been adequately investigated in Eastern countries. In addition, the reported studies in Asian patients were usually designed in small sample size, and resulted in inconsistent conclusions. The present systematic review and meta-analysis was therefore performed to evaluate the effectiveness of Montessori-based activities on the improvement of agitation in Asian patients with dementia. Results of the present study suggested that Montessori-based activities may reduce the frequency of agitation, especially in physical aggressive behaviors comparing to standard activities in Asian patients with dementia. However, the effectiveness of Montessori based activities on reduction of subcategorized agitated behaviors, including physical nonaggressive behaviors, and verbal aggressive behaviors may not be reliable as physical aggressive behaviors.

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