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### Featured Article

# Doll therapy for improving behavior, psychology and cognition among older nursing home residents with dementia: A systematic review and meta-analysis



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### ABSTRACT

*Objective*: To explore the effectiveness of doll therapy (DT) on behavior, psychology and cognition among older nursing home residents with dementia.

*Methods*: A systematic review and meta-analysis was conducted. Subgroup analyses were performed to determine whether the intervention characteristics influenced effect sizes.

Results: Ten studies met the inclusion criteria and were selected for qualitative and quantitative synthesis. The overall methodological quality was relatively high. DT significantly improved all behaviors [SMD=-0.42, P=0.01], including agitation [SMD=-0.94, P<0.001], apathy, irritability and wandering, and psychological states (i.e., pleasure, anxiety and depression). However, there was no significant difference in the improvement of cognition. Subgroup analyses revealed that the DT process employing empathy dolls and coordinating with caregivers was more beneficial for improving all behaviors (P=0.01; P=0.02).

Conclusion: DT significantly reduced behavioral and psychological disturbances among older nursing home residents with dementia. Specifically, administering empathy dolls and coordinating with caregivers may be the most appropriate and effective option.

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# Introduction

As the aging trend intensifies, the demands for primary medical care and assistance with daily living among older adults living in long-term care facilities and nursing homes (NHs) are expected to increase. Aging is associated with varying degrees of deterioration in cognitive function; approximately 48 % of older NH residents experience a clear-cut cognitive decline, and the dependency rate for care is as high as 30 %. <sup>1,2</sup> Institutionalized older adults are at greater risk of dementia due to a multidimensional deterioration in cognitive function. <sup>3</sup> As a neurodegenerative disease with many different etiologies, the main types include Alzheimer's disease (AD) and vascular dementia, which both begin with short-term memory loss and advance to long-term memory loss and confusion, decreased verbal and comprehension abilities, and changes in personality and behaviors. <sup>4</sup> According to statistical data, more than 10 % of older adults have

Alzheimer's disease and related dementias (ADRD), and this prevalence increases to 32 % among older NH residents. With the extensive losses from dementia, the burden and stress on caregivers and the healthcare system can be overwhelming.

During the clinical progression of dementia, the appearance of behavioral and psychological symptoms of dementia (BPSD) can further worsen the burden of the disease, and classic symptoms include agitation, apathy, irritability, wandering, anxiety, depression, delusions and hallucinations. 6 The most common behavioral disturbance among these symptoms is agitation, and the prevalence can be as high as 35 % to 70 %.7 Previous studies have indicated that the prevalence of behavioral and psychological disorders ranges from 40 % to 50 % among older NH residents. More than 80 % of institutionalized older adults with dementia experience the development of BPSD.<sup>8,9</sup> These issues could be related to the individual's unfulfilled needs due to the environment provided by NHs. The conflicts and changes in the psychosocial environment experienced during migration to NHs can lead to behavioral and psychological disturbances, which is known as "transfer trauma" or "relocation stress syndrome". 10 BPSD is associated with triggering falling, fracture, multiple trauma,

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disability and various accidents, which generate increased caregiver burden, abuse of psychotropic drugs, poor quality of life and higher rates of hospitalization and even mortality.<sup>8</sup>

Nonpharmacological therapies are considered the main method of diminishing the risk of BPSD and include emotion-oriented interventions (reminiscence therapy and reality orientation), sensory stimulation interventions (acupuncture, music therapy, multisensory stimulation therapy and transcutaneous electrical nerve stimulation), behavior management techniques and psychosocial interventions (animal-assisted therapy and multimodal exercises). 11 Doll therapy (DT) is also an effective nonpharmacological approach to reduce BPSD among older adults with moderate to severe dementia and has the advantages of being acceptable, affordable, available, and gradually used in NHs.<sup>12</sup> Previous systematic reviews have already indicated the effectiveness of DT for promoting and maintaining the affective relationship of attachment caregiving.<sup>13</sup> A DT program helps participants sustain verbal communication skills and focus on the surrounding environment, and it prevents social withdrawal by improving and maintaining social interaction.<sup>14</sup> Furthermore, nonverbal communication, such as eye contact, touch, exploration and caregiving behaviors, could also be increased by adopting care-related attitudes and activities, 15 thereby promoting a positive psychological state and minimizing the appearance of challenging behaviors and psychologies.

The concept of attachment describes the potential mechanism of the DT process in terms of its efficacy in the control of BPSD. Attachment theory considers that the human tendency to seek closeness and protection and the need to establish affective bonds when feeling vulnerable or insecure is an expression of the innate motivational system.<sup>16</sup> This tendency and requirement could persist over the whole life course and is particularly important for older NH residents affected by dementia, as this population is often exposed to feelings of personal vulnerability and loss, as well as experiences of separation.<sup>17</sup> Therefore, BPSD might be interpreted as attachment requests, while DT provides the possibility of establishing the affective bond needed in a stressful situation to reduce behavioral and psychological disturbances. The dolls are designed to recreate the sensation of touching, staring at, and holding a child and thus can be perceived as a translational object, catalyze participants' attention and reduce attachment requests. 18 Through communication and interaction with the dolls, participants can be prompted to substitute caregiving behaviors for challenging behaviors.

A recent meta-analysis revealed that DT can overcome the limitations of traditional interventions, improve the psychological state and communication skills of patients with dementia, and diminish challenging and aggressive behaviors. 19 However, there is insufficient evidence to support the effects on older NH residents with dementia. Compared with community-dwelling or hospitalized individuals, institutionalized older adults are more likely to experience a worsening of their behavioral and psychological conditions due to the particularity of the environment. Although a few studies have examined the effects of DT on cognition, <sup>20</sup> the available evidence is inadequate to reach a consensus. No meta-analysis has summarized the effects of DT on behavior, psychology and cognition among older NH residents with dementia. Therefore, the purpose of this systematic review and meta-analysis was to explore the effectiveness of DT in reducing dementia-related behavioral and psychological disturbances as well as ameliorating cognitive function among older adults with dementia in NHs. Subgroup analyses were conducted based on intervention characteristics (duration, cycle, types of dolls, and training mode and control measures) to optimize the selection of DT programs.

### Methods

This systematic review was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Supplementary file 1). It was registered at the International Prospective Register of Systematic Reviews (PROSPERO) under registration number CRD42023452060.

### Search strategy

The PubMed, Ovid (MEDLINE), Embase, Cochrane Library, CINAHL (EbscoHOST), and Web of Science databases were searched from inception until July 25, 2023. Google Scholar was also searched to identify literature that may have been omitted. The search was conducted using Medical Subject Headings (MeSH) and free text words, and language or publication year restrictions were not applied. The article type was restricted to randomized control trials (RCTs) and quasiexperimental studies. Moreover, we evaluated the gray literature, the reference lists of the screened studies, and articles of forward citations to identify additional eligible studies. The search strategy details are presented in Supplementary file 2.

### Inclusion and exclusion criteria

The Population, Intervention, Comparison, Outcome, Study design (PICOS) framework was used to formulate the selection criteria: (1) The population was individuals aged >65 years who had a dementia diagnosis in accordance with the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) and residing in NHs, long-term care or assisted living facilities (residence duration ≥3 months); there were no restrictions on cognitive conditions, but participants were required to possess the motor skills necessary to interact with a doll and sufficient visual and auditory function and communication skills. (2) The intervention comprised DT, and the type of dolls was not restricted (e.g., empathy dolls, lifelike dolls, and newborn or reborn dolls). (3) The comparison groups received training that was not in any form of DT, standard care or no intervention. (4) The primary outcomes included any behavior-, psychology-, or cognition-related targets. (5) The eligible study designs were randomized controlled trials (RCTs) or quasiexperimental studies.

The exclusion criteria were as follows: (1) participants with severe sensory disorders; (2) dolls without a realistic appearance or that were stuffed dolls; (3) unable to access the full text; (4) mixed method design; (5) secondary analysis; (6) incomplete data for analysis; and (7) conference abstracts, case reports, gray literature, study protocols or review literature.

# Study selection and data extraction

Two researchers initially separately screened the literature by evaluating the titles and abstracts in accordance with the predesigned criteria. The literature that met the eligibility criteria was then selected for full-text reading and targeted analysis. Disagreements were resolved by consulting a third researcher to reach a consensus. The following data were extracted: (1) basic information (author names, publication year, country); (2) participant demographic data (characteristics, age, sample size and sex); (3) intervention characteristics (duration and cycle, types of dolls, training mode and control measures); and (4) outcome measurements (behavior-, psychologyand cognition-related indicators). All data were cross-checked by reviewers.

### Quality assessment

The Cochrane risk of bias tool was used to evaluate the quality of the studies.<sup>21</sup> Seven items were assessed: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. Each item was rated as having "high risk",

"unclear risk" or "low risk". Studies that met all of the above criteria were considered high-quality studies. Furthermore, the level of evidence for outcome indicators was evaluated by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.<sup>22</sup> Each outcome was graded as very low, low, moderate or high level.

### Statistical analysis

RevMan 5.3 (Cochrane Collaboration, Oxford, UK) statistical software was employed to perform the meta-analysis. The standard mean difference (SMD) or mean difference (MD) was calculated for continuous data, relative risks (RRs) were calculated for counting data, and the effect size was assessed using 95 % confidence intervals (CIs). The Q value and  $I^2$  value were used to determine heterogeneity among the studies.  $I^2$  values of 25 %, 50 % and 75 % indicated low, moderate and high heterogeneity, respectively. The fixed effect model was applied if the heterogeneity among the results was not significant ( $P \ge 0.1$ ,  $I^2 < 50$  %); otherwise, the random effect model was selected (P < 0.1,  $I^2 > 50$  %). Stata 14.0 statistical software (StataCorp, LLC, College Station, TX, USA) was used to analyze potential publication bias, and the trim and fill methods were also carried out for verification. Subgroup analyses were conducted to explore betweenstudy heterogeneity. Sensitivity analysis was performed to test the reliability of the results. Descriptive analyses were used for statistical data that could not be combined. P<0.05 was considered to indicate statistical significance.

#### Results

### Study selection

A total of 360 studies were initially selected by the predesigned retrieval strategy from six databases and Google Scholar Search. After removing 128 duplicate studies with EndNote software, the remaining 232 studies were screened by title and abstract, and 179 studies were excluded because they did not meet the eligibility criteria. Then, 53 full-text studies were further screened, and 43 were subsequently excluded for several reasons: noncorrelation outcomes (n=17); not RCTs or quasiexperimental studies (n=12); mixed method designs (n=5); unable to access the full text (n=4); secondary analysis of initial data (n=2); and incomplete data for meta-analysis (n=3). Ultimately, 10 studies<sup>23–32</sup> were included for qualitative and quantitative synthesis. The PRISMA flow diagram of the study selection process is illustrated in Fig. 1.

### Basic characteristics of studies and participants

The 10 included studies were published from 2006 to 2022 and were conducted in Australia (n=1), Italy (n=3), Israel (n=1), Korea (n=1), Switzerland (n=2), Turkey (n=1) and the United Kingdom (n=1). A total of 573 older adults with dementia met the eligibility criteria in the included studies, and the participants' mean (SD) age ranged from  $82.4 (5.7)^{26}$  to  $89.7 (8.4)^{28}$  years. The majority of participants were females (83.66 %), and two studies did not report the sex proportion. Two studies were conducted in long-term care or

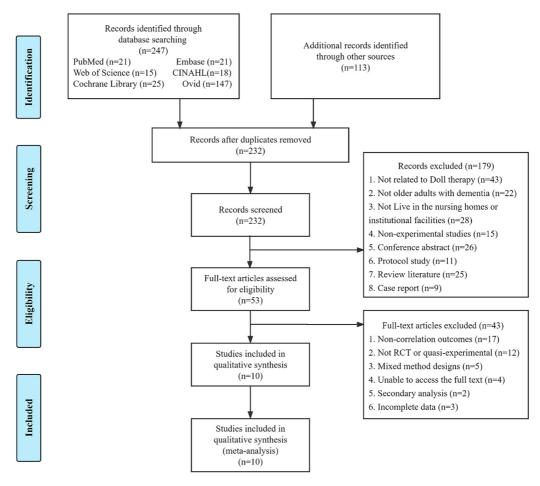


Fig. 1. PRISMA flow diagram of the study selection process.

social care facilities, <sup>28,32</sup> one was performed at a residential care center, <sup>27</sup> two were carried out in other social institutions, <sup>25,26</sup> and the remainder were conducted in NHs. Most of the participants had moderate to severe dementia, one study involved mild cognitive impairments in older adults, <sup>26</sup> and one included older adults suffering from AD and vascular dementia. <sup>31</sup> The participants' effective adherence rates ranged from 82.69 % to 100 %. The reasons for loss to follow-up mainly included transfer (n=3), <sup>27</sup> refusal to participate (n=3), <sup>24</sup> neutral or negative interaction with the doll (n=6), <sup>24</sup> unwillingness to continue (n=4), <sup>23</sup> and terminal disease (n=1). <sup>23</sup> The methodological characteristics of the included studies are summarized in Table 1.

### Doll therapy features

The dolls mainly included two types as intervening measures. Three study designs involved empathy dolls, which were characterized as eliciting psychological reactions and providing opportunities for pleasurable sensory experiences through recreating the sensations of touching, staring at and holding a child.<sup>23,25,31</sup> Five studies used lifelike dolls, which were made with smiles and eyes that could open and close to convey calmness and peacefulness, but they did not cry or laugh.<sup>24,28–30,32</sup> Five study designs reported that the training mode was coordinated with caregivers, who guided, supervised and validated DT sessions, helping the participants to understand the program structure and ensuring the safety and comfort of the sessions.<sup>23,25,26,29,31</sup> Five studies employed health education, and DT applications were introduced through pictures, videos or brochures within the acceptable understanding of the participants or led by a trained research assistant.<sup>24,27,28,30,32</sup> The duration of each training session ranged from 0.5 to 4 hours, and the total intervention cycle lasted from 2 to 72 weeks. Most of the control groups received standard care or no intervention, and the remaining studies were related to sham intervention, 23,31 standard treatment, 24,28 and handwarmer.<sup>27</sup> The DT features of the included studies are illustrated in Table 1.

## Outcome measurements

The main outcome measures focused on behavior, psychology and cognition. The most common measurements were the Neuropsychiatric Inventory Scale (NPI) for evaluating behavioral outcomes.<sup>24</sup> It includes 12 behavioral domains, and the frequency (1=rarely to 4=very often) and severity (1=mild to 3=severe) are reported. The final score is found by multiplying these values (0-144), with higher scores indicating more behavioral disturbances. The Observed Emotion Rating Scale (OERS) and Quality of Life in Late-Stage Dementia (QUALID) were selected for the evaluation of psychological state.<sup>28,29</sup> The Mini-Mental Status Examination (MMSE) was primarily used to assess cognition.<sup>26</sup> It rates 11 items under 5 domains (30-point scale), with higher scores indicating more severe cognitive impairment. Finally, we extricated the different outcome measurement information according to similar structures and methods to create an outcome indicator that could be assessed (Table 1).

# Methodological quality

The included studies followed the principle of randomization allocation, reasonable study design and baseline comparison; follow-up loss and outcome measurement data were completely reported, and the overall quality was at a high level. Among the 10 studies, 7 studies reported random sequence-generating methods that mainly included drawing lots, computerized sequence generators, and computer-based block randomization.<sup>23–28,30</sup> Five studies implemented procedures for allocation concealment, mainly employing the sealed envelope method.<sup>23,25–28</sup> To ensure the successful completion of the

DT program, only two studies fulfilled the blinding of participants and interveners, <sup>25,28</sup> but seven studies completed the assessor-blind methods for data collection. <sup>23–26,28,31,32</sup> Almost all studies reported complete data, indicating that there was minimal possibility of selective reporting bias or other bias. The quality assessment of the included studies is summarized in Table 2. Levels of evidence for outcome indicators were assessed as moderate (n=1) and low (n=2). The low level of evidence was mainly ascribed to the high heterogeneity and nonimplementation of allocation concealment and blinding methods, and the sample size was limited. The levels of evidence are illustrated in Supplementary file 3.

### Meta-analysis of outcome measures

The primary indicators were behavior (agitation, apathy, irritability and wandering), psychology (pleasure, anxiety and depression), and cognition outcomes.

### **Behavior**

The behavioral indicators included agitation, apathy, irritability and wandering. Seven studies were compared in terms of whole behavior, and one study was excluded from this meta-analysis because it reported a different calculation method for the outcome indicator. The results revealed that DT had a significant effect on improving the overall behavior of older NH residents with dementia [SMD=-0.42, 95 % CI (-0.74, -0.10), Z=2.54, P=0.01] (Fig. 2). Egger's tests revealed that there was no significant publication bias (P=0.656). The trim-and-fill method imputed one study, and the results were subjected to trim-and-fill adjustment [SMD=-0.529, 95 % CI (-0.865, -0.192)], as shown in Table 3.

# Agitation

Three studies were compared in terms of agitation.  $^{25,28,32}$  The results showed that DT significantly improved the agitation of older NH residents with dementia [SMD=-0.94, 95 % CI (-1.36, -0.51), Z=4.27, P<0.001] (Fig. 2). Egger's test revealed that there was no potential publication bias (P=0.577), as shown in Table 3.

### Apathy

Three studies compared participants' apathy behavior. Molteni et al.<sup>23</sup> reported that DT significantly reduced the apathy of older adults with dementia in NHs (z=-3.418, P<0.001). Santagata et al.<sup>24</sup> observed a significant amelioration of apathy symptoms among the participants through training (P=0.0011). Meanwhile, Balzotti et al.<sup>26</sup> found that the participants' interaction behaviors, social contacts and verbalization were significantly enhanced (z=2.01, P=0.04).

### Irritability

Three studies compared participants' irritability behavior. Molteni et al.<sup>23</sup> reported that DT exerted a significant reduction in disruptive and aggressive behaviors among older adults with dementia in NHs (z=-2.679, P<0.05). Balzotti et al.<sup>26</sup> verbalized that participants used fewer swear words, shouted less, and exhibited less obsessive behavior (z=2.02, P=0.04). Similarly, Shin et al.<sup>29</sup> observed that the participants were less irritable while touching, looking at and holding the lifelike doll (t=-16.31, P<0.01).

### Wandering

Three studies compared participants' wandering behavior. Molteni et al.<sup>23</sup> reported that DT significantly reduced the wandering of older adults with dementia in NHs (z=-2.231, P<0.05). Santagata et al.<sup>24</sup> verbalized a significant improvement in wandering symptoms (P=0.0207). Likewise, Shin et al.<sup>29</sup> found that the episodes of erratic wandering decreased among the participants (t=-17.76, P<0.01).

**Table 1**Characteristics of the included studies

Author (year)	Methods	Participants			Outcomes Measurement		
Country		Characteristics Age (years)	Sample Size (Male/Female)	Experimental Group	Control Group	Duration and Cycle	
Molteni et al. (2022) <sup>23</sup> Switzerland	Single-blinded RCT	Older adults with dementia living in nursing homes EG: $86.9 \pm 5.9$ CG: $88.4 \pm 5.5$	Total=129 EG=64 (0/64) CG=65 (0/65)	Design: Doll Therapy     Content: Empathy doll (Recreating the sensation of touching, looking at, and holding a child)     Mode: Coordinated with caregiver (Guided and validated sessions)	Sham intervention: Nonanthropomorphic object (Soft foam rubber cube covered with a col- ored and velvety tex- tile)	Hours per session: 1 Total: 72 weeks	Behavior: NPI—NH     Apathy     Irritability     Wandering     Psychology:     NPI—NH Distress     Anxiety
Santagata et al. (2021) <sup>24</sup> Italy	RCT	Older nursing home residents with dementia EG: $87.0 \pm 7.0$ CG: $86.0 \pm 6.0$	Total=52 EG=26 (5/21) CG=26 (4/22)	<ul> <li>Design: Doll Therapy</li> <li>Content: Lifelike doll</li> <li>Mode: Health education</li> <li>(Provide a brochure on BPSD in dementia)</li> </ul>	Standard treatment: According to standard clinical care in choos- ing pharmacological intervention	Hours per session: 2 Total: 12 weeks	<ul><li>Behavior: NPI</li><li>Apathy</li><li>Wandering</li><li>Cognition: SPMSQ</li></ul>
Yilmaz et al. (2020) <sup>25</sup> Turkey	Double-blinded RCT	Institutionalized older adults with moderate $-$ to $-$ severe dementia EG: $83.53 \pm 5.89$ CG: $82.30 \pm 7.55$	Total=29 EG=15 (5/10) CG=14 (9/5)	<ul> <li>Design: Doll Therapy</li> <li>Content: Empathy doll</li> <li>(The dolls were named, dressed, had hats and socks on, and combed their hair)</li> <li>Mode: Coordinated with caregiver (Guided and supervised sessions)</li> </ul>	No intervention	Hours per session: 2–3 Total: 8 weeks	<ul><li>Behavior: NPI</li><li>Agitation: CMAI</li><li>Cognition: SMMSE</li></ul>
Balzotti et al. (2019) <sup>26</sup> Italy	RCT	Older adults with mild cognitive impairment living in social institutions EG1: $82.4 \pm 5.7$ EG2: $87.8 \pm 6.6$ CG: $86.9 \pm 5.2$	Total=30 EG1=10 EG2=10 CG=10	<ul> <li>Design: EG1: Gestural-verbal treatment</li> <li>EG2: Doll Therapy</li> <li>Content: Five steps</li> <li>Mode: Coordinated with caregiver (Presented, interacted and guided sessions)</li> </ul>	No intervention	Hours per session: 1 Total: 12 weeks	<ul> <li>Behavior: NPI-Q</li> <li>Apathy</li> <li>Irritability</li> <li>Psychology</li> <li>Depression</li> <li>Cognition: MMSE</li> </ul>
Cantarella et al. (2018) <sup>27</sup> Italy	RCT	Older adults with severe dementia living in a residential care center EG: $85.31 \pm 6.21$ CG: $87.23 \pm 5.03$	Total=29 EG=16 CG=13	Design: Doll Therapy     Content: Discussion study protocol—Pretest assessment—Observation phase—Experimental phase—Posttest assessment     Mode: Health education	Hand-warmer	Hours per session: 1 Total: 4 weeks	• Behavior: NPI-BPSD
Moyle et al. (2018) <sup>28</sup> Australia	Double-blinded RCT	Older adults with dementia in long-term care facilities EG: $86.1 \pm 8.6$ CG: $89.7 \pm 8.4$	Total=33 EG=18 (0/18) CG=15 (0/15)	Design: Doll Therapy     Content: Lifelike doll     Mode: Health education (Trained research assistant introduce and remove doll)	Standard facility care	Hours per session: 0.5 Total: 3 weeks	<ul> <li>Behavior</li> <li>Agitation: CMAI-SF</li> <li>Psychology: OERS</li> <li>Pleasure</li> <li>Cognition: MMSE</li> </ul>
Shin et al. (2015) <sup>29</sup> Korea	Prepost	Older nursing home residents with dementia EG: 82.54 ± 7.45	Total=62 EG=62 (9/53)	<ul> <li>Design: Doll Therapy</li> <li>Content: Lifelike doll</li> <li>Mode: Coordinated with caregiver (Guided and feedback sessions)</li> </ul>	NA	Hours per session: 1 Total: 12 weeks	Behavior: Ad hoc questionnaire     Irritability     Wandering     Psychology: QUALID     Pleasure     Anxiety     Depression
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Author (year)	Methods	Participants			Interventions		Outcomes Measurement
Country		Characteristics Age (years)	Sample Size (Male/Female)	Experimental Group	Control Group	Duration and Cycle	
Cohen–Mansfield et al. (2015) <sup>30</sup> Israel	Exploratory study	Older adults with dementia residing at a nursing home EG: 85.9 ± 8.6 CG: 85.9 ± 8.6	Total=165 EG=89 (24/65) CG=76 (21/55)	Design: Doll Therapy     Content: Lifelike doll     (Trial phase and treatment phase)     Mode: Health education	No intervention	Hours per session: 4 Total: 2 weeks	• Behavior: CAR
Pezzati et al. (2014) <sup>31</sup> Switzerland	Pilot study	Older nursing home residents with Alzheimer's disease and vascular dementia EG: 85.8 ± 7.3 CG: 83.6 ± 7.4	Total=10 EG=5 (1/4) CG=5 (0/5)	Design: Doll Therapy     Content: Empathy doll     (Recreating the sensation of touching, looking at and holding a child)     Mode: Coordinated with caregiver	Sham intervention: Nonanthropomorphic object (Soft foam rubber cube covered with a col- ored and velvety tex-	Hours per session: 1 Total: 4 weeks	• Behavior: NPI
James et al. (2006) <sup>32</sup> UK	Pilot study	Older adults with dementia living in an EMI social care home EG: 75–94 CG: 75–94	Total=34 EG=14 (2/12) CG=20 (4/16)	Design: Doll Therapy     Content: Lifelike doll     (Pick up, hold and interact with dolls)     Mode: Health education     (Research staff introduce and feedback sessions)	No intervention	Hours per session: 1 Total: 12 weeks	Behavior: Ad hoc questionnaire     Agitation

EG, Experimental Group; EMI, Elderly Mentally III; MMSE, Mini–Mental Status Examination; NPI, Neuropsychiatric Inventory Scale; NPI—BPSD, Neuropsychiatric Inventory—BPSD Scale; NPI—NH, Neuropsychiatric Inventory Questionnaire; NA, Not Applicable; OERS, Observed Emotion Rating Scale; QUALID, Quality of Life in Late—Stage Dementia; RCT, Randomized Controlled Trial; SMMSE, Standardized Mini—Mental Status Questionnaire. EBSD. Behavioral and Psychological Symptoms of Dementia; CMAI, Cohen—Mansfield Agitation Inventory Scale; CMAI—SF, Cohen—Mansfield Agitation Inventory Scale; CMAI—COhen—Mansfield Agitation Inventory—Short Form; CAR, Change Assessment Rating; CG, Control Group;

# Psychology

Four studies reported the benefits of DT in providing psychological support.  $^{23,26,28,29}$  Two of them found that DT had a significant effect on positive psychology (i.e., pleasure) among older NH residents with dementia (Moyle et al., F=4.400, P=0.044; Shin et al., t=4.28, P<0.01).  $^{28,29}$  Four studies were compared in terms of negative psychology (i.e., anxiety and depression). Two of them reported that DT significantly diminished anxiety and discomfort (Molteni et al., z=-3.929, P<0.001; Shin et al., t=-18.05, P<0.01).  $^{23,29}$  Two studies found significant improvements in depression (Balzotti et al., z=2.02, P=0.04; Shin et al., t=-18.22, t<-0.01).  $^{26,29}$ 

# Cognition

Four studies were compared in terms of cognition. Page 24–26,28 The results showed that DT had no significant effect on improving the cognitive function of older adults with dementia in NHs [SMD=-0.23, 95 % CI (-0.57, 0.11), Z=1.33, P=0.18] (Fig. 2). Egger's test revealed that there was no potential publication bias (P=0.145). The trim-and-fill adjustment [SMD=-0.286, 95 % CI (-0.575, -0.003)] was performed by imputing one study, as shown in Table 3.

## Subgroup analysis

Our results showed that DT had significant effects on behavior and psychology among older NH residents with dementia. Therefore, subgroup analyses were conducted to determine whether the intervention characteristics influenced the effect sizes and to solve the between-study heterogeneity. The subgroup analyses revealed that the empathy doll was significantly superior to the lifelike doll in improving overall behavior (P=0.01). The DT training mode, conducted in coordination with caregivers, was more effective than health education in improving behavior (P=0.02). However, the effects did not differ based on training duration, cycle, or control measures (Fig. 3).

### Discussion

Given the intensification of the aging trend and the increasing demand for institutionalized facilities, there is an urgent need for an integrated, effective and sustainable option to provide psychological and cognitive care to reduce behavioral and psychological disturbances among older adults with dementia. DT is a nonpharmacological technique with the aim of promoting attachment and companionship among patients with dementia to improve their wellness and minimize the appearance of challenging behaviors and psychologies. <sup>19</sup> This meta-analysis was conducted to explore the effectiveness of DT for improving behavior, psychology and cognition among older NH residents with dementia. Ten studies reported that DT significantly reduced behavioral disturbances and improved the psychological state among institutionalized older adults with dementia. However, there was no significant difference in the improvement of cognitive function.

# Effects of the DT process on behavioral disturbances

The emergence of BPSD seriously affects the presentation and progression of dementia among older NH residents and is associated with greater functional impairment, accelerated cognitive decline and increased caregiver burden. The current meta-analysis revealed that the DT process significantly improved overall behavior, including agitation, apathy, irritability and wandering, among older adults with dementia in NHs. Our findings are in line with other studies reporting that DT was effective in decreasing negative behaviors such as

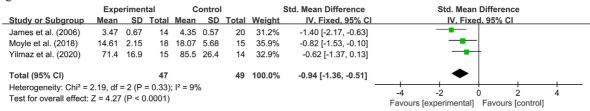
**Table 2**Quality assessment of included studies

Author (year)	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Molteni et al. (2022) <sup>23</sup>	low risk	low risk	high risk	low risk	low risk	low risk	low risk
Santagata et al. (2021) <sup>24</sup>	low risk	unclear risk	unclear risk	low risk	low risk	low risk	low risk
Yilmaz et al. (2020) <sup>25</sup>	low risk	low risk	low risk	low risk	low risk	low risk	low risk
Balzotti et al. (2019) <sup>26</sup>	low risk	low risk	unclear risk	low risk	low risk	low risk	low risk
Cantarella et al. (2018) <sup>27</sup>	low risk	low risk	high risk	unclear risk	low risk	low risk	low risk
Moyle et al. (2018) <sup>28</sup>	low risk	low risk	low risk	low risk	low risk	low risk	low risk
Shin et al. (2015) <sup>29</sup>	high risk	high risk	unclear risk	unclear risk	low risk	unclear risk	unclear risk
Cohen–Mansfield et al. (2015) <sup>30</sup>	low risk	unclear risk	unclear risk	unclear risk	unclear risk	low risk	unclear risk
Pezzati et al. (2014) <sup>31</sup>	unclear risk	unclear risk	unclear risk	low risk	low risk	low risk	unclear risk
James et al. (2006) <sup>32</sup>	unclear risk	unclear risk	unclear risk	low risk	unclear risk	unclear risk	unclear risk

### A Behavior

Experimental			tal	С	ontrol			Std. Mean Difference		Std. Mea	n Differ	ence	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI		IV, Ran	dom, 95	% CI	
Cantarella et al. (2018)	0.95	0.41	16	1.24	0.45	13	12.2%	-0.66 [-1.41, 0.10]		_	_		
Cohen-Mansfield et al. (2015)	4.12	0.83	89	4.25	0.78	76	27.5%	-0.16 [-0.47, 0.15]			-		
Molteni et al. (2022)	21.94	9.7	64	27.54	7.1	65	25.3%	-0.66 [-1.01, -0.30]		-	-		
Pezzati et al. (2014)	21.2	7.4	5	21.8	13.3	5	5.7%	-0.05 [-1.29, 1.19]		-	+	•	
Santagata et al. (2021)	48.3	12	26	48.2	13	26	17.9%	0.01 [-0.54, 0.55]			+		
Yilmaz et al. (2020)	34.7	16.3	15	58.9	25.7	14	11.4%	-1.10 [-1.89, -0.31]		•	-		
Total (95% CI)			215			199	100.0%	-0.42 [-0.74, -0.10]		•	•		
Heterogeneity: Tau <sup>2</sup> = 0.07; Chi <sup>2</sup> = 10.25, df = 5 (P = 0.07);   <sup>2</sup> = 51%									-1	-2		<del></del>	
Test for overall effect: Z = 2.54 (P = 0.01)								Favours	experimenta	l] Favo	urs [contro	ıı -	

### B Agitation



# C Cognition

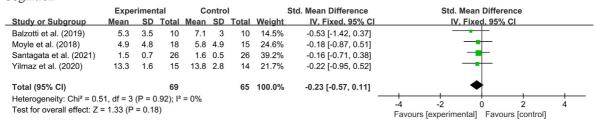


Fig. 2. Forest plots of main outcomes.

agitation, apathy and aggression in patients with dementia.<sup>33</sup> Mackenzie et al.<sup>15</sup> pointed out that 93 % of caregivers of institutionalized patients with dementia stated that DT decreased irritability and wandering and improved attitude and communication skills. The retrospective study by Ellingford et al.<sup>34</sup> reported that after the DT

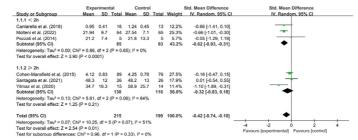
process, more positive behaviors emerged, while negative behaviors, such as agitation and aggression, declined.

The potential benefits can be ascribed to the dolls having the characteristics of being cute, soft and comfortable, which could relax individuals and conjure affective resonance through contact and

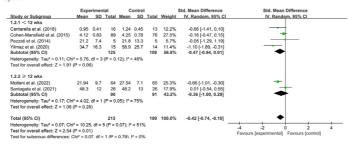
**Table 3**Meta—analysis of outcome indicators included in the studies

Outcome indicators	Study detail	tail Effect measure Heterogeneity Publication bias					
	Studies (n)	SMD (95 % CI)	P value	I <sup>2</sup> (%)	Egger P value	Trim-and-fill imputed studies	Trim-and-fill adjusted SMD (95 % CI)
Behavior	6	-0.42 (-0.74, -0.10)	0.01	51	0.656	1	-0.529 (-0.865, -0.192)
Agitation	3	-0.94(-1.36, -0.51)	< 0.001	9	0.577	0	_
Cognition	4	-0.23 (-0.57, 0.11)	0.18	0	0.145	1	-0.286 ( $-0.575$ , $-0.003$ )

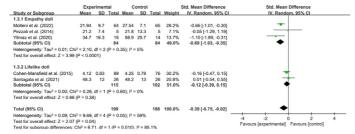
### A Duration



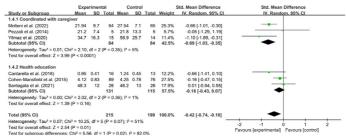
### B Cycle



### C Types of dolls



# D Training mode



### E Control measures

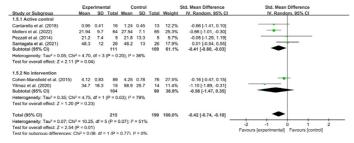


Fig. 3. Subgroup analysis of intervention characteristics.

interaction with them. Agitation is regarded as a craving for attachment, and the dolls provided as a therapeutic tool force participants to focus on the care needs of the dolls, thereby reducing the occurrence of agitation and irritable behaviors.<sup>25</sup> Additionally, the dolls can be conceptualized as a relational subject, prompting a series of

proactive behaviors. This process enhances the participants' attentive abilities, achieves affective alternation and clearly allocates significant relationships with the dolls in a safe environment, leading to the activation of the caregiving system. Therefore, more frequent and longer duration needs and desires for exploration were elicited

with regard to the relational value, consequently decreasing apathic and wandering behaviors. Protection and safety factors are essential for individuals based on attachment theory. The DT process enables communication, interaction and care between participants and dolls and satisfies participants' attachment needs, thus improving overall behavior and decreasing behavioral disturbances.

### Effects of the DT process on psychological state

Psychological disturbances are particularly pronounced among older NH residents with dementia, placing a growing burden on the health service system. The meta-analysis revealed that the DT process significantly improved the psychological state of this population. Our results are consistent with previous findings that DT can be used for rehabilitative purposes to decrease the signs of psychological discomfort (i.e., anxiety, depression and frustration) and to improve pleasure-related emotions, expressive ability and communication willingness among patients with moderate-to-severe dementia. 37,38 The benefits can be attributed to the active interaction and communication with the dolls, which could motivate the participants to experience the positive psychologies associated with parent-baby relationships again.31 From the perspective of neuroendocrinology based on the attachment theory framework, there is a preference for social familiarity when seeking to create supportive relationships mediated by oxytocin, which is involved in the mechanism for attachment formation and coping with stress.<sup>39</sup> Therefore, DT contributed to the formation of attachment relationships through progressive exposure, interaction and familiarity with the dolls, which resulted in a reduced negative psychological state. Furthermore, DT could create a therapeutic atmosphere to stimulate sensory perception, promoting the development of a positive psychological state, and actively interacting with caregivers and the external environment.<sup>29,40</sup>

# Effects of the DT process on cognitive function

The progression of dementia is frequently accompanied by varying degrees of cognitive decline, and the variability of cognitive performance is affected by multiple factors, which are mainly associated with poor stimulation of perceptive and executive function.<sup>41</sup> The meta-analysis showed that application of the DT process did not effectively improve cognition among older NH residents with dementia, which is in line with previous findings.<sup>38</sup> The potential mechanism was that improvements in cognition require attention, orientation, memory, and construction tasks that activate different sensory media to improve perceptive and executive functions, such as attention, reaction time, short-term memory, and information processing speed. DT was designed to reduce the participants' attachment requests and establish affective bonds.<sup>18</sup> Although it helps to improve attention, touching, staring at, and holding the dolls did not effectively ameliorate executive ability. However, another view considered that interacting with dolls can stimulate perception and promote communication with the external environment, which can activate the brain's residual memory to a certain extent.<sup>13</sup> Therefore, we suggest incorporating more basic studies in the future to observe the effect of DT on cognition among older NH residents with dementia.

# Characteristics of interventions

The subgroup analyses revealed that the types of dolls and training mode of DT had moderating effects on the improvement of overall behavior among older NH residents with dementia. Therefore, indepth analyses were constructed to determine the optimal strategy.

Effects of the DT type on overall behavior

The types of dolls employed by the DT process are manifold and varied, but the dominant types are empathy dolls and lifelike dolls. The differences between design types may produce different effects on the outcome indicators. Unexpected anecdotal findings from the subgroup analysis showed that DT sessions employing empathy dolls resulted in more significant improvement in all behaviors than those using lifelike dolls. The potential mechanism is that the presentation of empathy dolls elicits the participants' psychological reactions, provides opportunities for pleasurable sensory experiences and promotes caring and exploratory behaviors to build a caregiving relationship between the participants and the doll.<sup>23,42,43</sup> Consistent with the theoretical framework of attachment, DT facilitates perceptions of security by creating a situation in which the participants are gradually exposed to, interact with and become familiar with the dolls, which contributes to the formation of attachment relationships, reduces behavioral disturbances, and improves the participants' communication abilities, self-esteem and overall quality of life. 31,44 In contrast, the use of lifelike dolls is more concerned with calming emotions to minimize the appearance of challenging behaviors.<sup>28,4</sup> However, the establishment of affective bonds and anthropomorphic relationships in their designs is not perfect, resulting in differences in the generation of attachment; 46 thus, the effects may be diminished.

## Effects of the DT mode on overall behavior

To facilitate the implementation of the DT process, the design of the training mode must account for participants' personal rights, preferences, attitudes and beliefs.<sup>29</sup> Our subgroup analysis showed that the DT process coordinated with caregivers had a more significant effect on all behaviors than health education. Although previous studies have confirmed the effectiveness of pictures, videos, brochures and guidance by trained research assistants, 15,47 this cannot replace the role of caregivers who introduce, guide and explain the procedures to ensure correct execution and supervise, validate and feedback the significance of participants' interaction with the dolls.<sup>25,26</sup> While incrementally fostering autonomy, this process can also provide a source of security to improve the quality of caregiving relationships. Caregivers could recognize the participants' interests, attitudes and preferences, assist in decision-making and provide information and support to ensure their rights to choose autonomously, guarantee the security of the procedures and implement the person-centered intervention.<sup>23,48</sup> Based on the initial reactions of the participants, engaging with the doll and providing necessary assistance may be the optimal guidance to determine whether the approach is appropriate. Respect for autonomy could resolve any ethical issues that may be encountered in the DT process, such as viewing it as a childish behavior and the difficulties in finding the target individuals for treatment. Conversely, caregivers who regarded sessions as a daily duty gradually became acquainted with the intervention mechanisms and provided continuous supervision and feedback, which also helped to reduce their distress and improves the quality of personalized care.<sup>49</sup>

# Strengths and limitations

This review systematically elucidated the effectiveness of DT on behavior, psychology and cognition among older NH residents with dementia. The optimal scheme was determined through in-depth analyses. Nevertheless, there are still some limitations to our study. First, the high proportion of female participants may have triggered sex-specific responses caused by the imbalance in the male-female ratio. Second, blinding is difficult to achieve because participants and interveners need to know the DT process, which might bias the results. Third, because of the lack of standardized tools to assess the

affective-relational dynamics of attachment caregiving among the participants, some studies used only observational measures. Future studies should develop standardized and objective outcome measures. Laboratory assessments can detect subtle changes that cannot be measured by clinical tests to avoid subjective effects. Fourth, the communications and interactions between health care professionals and participants may produce a calming effect during the DT process; therefore, the interaction effects are also difficult to identify. Finally, the partial included studies merely employed descriptive analyses due to methodological limitations, which may limit the credibility of the results.

### Conclusion

This systematic review and meta-analysis demonstrates that the DT process significantly diminished behavioral disturbances and improved the psychological state among older NH residents with dementia, which can provide a reference for future research. However, the mechanism behind the effectiveness of DT on cognition needs further exploration. The crucial findings were that employing empathy dolls and coordinating with caregivers may be the most appropriate and effective strategy. Currently, DT procedures are advocated as a cost-efficient, sustainable and safe approach to ameliorate behavioral and psychological symptoms in older adults with dementia. Future studies should focus on multicenter study design and blind procedures, unify outcome indicators and precise measure outcomes, and identify the interaction effects between health care professionals and participants to further consolidate the effectiveness of DT among older NH residents with dementia.

# **Ethical approval**

Not applicable.

### Informed consent

Not applicable.

# **Data availability**

The data utilized in this study are available in published articles.

### **Declaration of Competing Interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

# **Supplementary materials**

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.gerinurse.2023.10.025.

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