International Journal of Nursing Studies 145 (2023) 104530

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/locate/ns

The effectiveness of a therapeutic robot, 'Paro', on behavioural and psychological symptoms, medication use, total sleep time and sociability in older adults with dementia: A systematic review and meta-analysis

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ARTICLE INFO

Article history:
Received 11 September 2022
Received in revised form 15 May 2023
Accepted 15 May 2023

Keywords:
Therapeutic robot
Paro
Dementia
Older adults
Anxiety
Agitation
Depression
Apathy
Systematic review
Meta-analysis

ABSTRACT

Objective: To evaluate the effectiveness of a therapeutic robot, 'Paro', on anxiety, agitation, depression, apathy, medication use, total sleep time, and sociability among older adults with dementia.
Design: Systematic review and meta-analysis with narrative synthesis.
Setting and participants: Older adults aged 60 years and above with any form of dementia in the community, nursing homes, or care facilities.
Methods: A three-step search strategy was conducted by two independent reviewers. Nine databases were searched (January 2003 to November 2022). Randomised controlled, crossover, and cluster trials on Paro for older adults with dementia published in English were included. All relevant trials were screened and assessed for risk of bias. Data were extracted using the Cochrane data collection form. The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) was used to assess the quality of evidence.
Results: In total, 12 articles involving 1461 participants were included. Results of the meta-analysis showed that Paro had a moderate effect on medication use (SMD: −0.63) and small effect on anxiety (SMD: −0.17), agitation (SMD: −0.27) and depression (SMD: −0.40). However, Paro exhibited negligible effect on total sleep time (SMD: −0.12). The overall quality of evidence for all outcomes were graded as low due to methodological limitations, small sample size, and wide confidence intervals. Narrative synthesis suggested that Paro reduced apathy and increase sociability.
Conclusion and implications: Paro could be a beneficial non-pharmacological approach to improve behavioural and psychological symptoms of dementia, reducing medication use, and increasing sociability for older adults with dementia. However, the results should be interpreted with caution as limited studies were available. Additionally, there were a variety of approaches across the studies (i.e. group and individual interventions, facilitated and non-facilitated) which made it difficult to determine which interventional approach is optimal to produce beneficial effects of Paro. Hence, more rigorous studies with a larger sample size are needed to fully understand the mechanism and effectiveness of Paro in older adults with dementia.
The protocol was registered on PROSPERO (CRD42022296504).

What is already known

- A therapeutic robot, 'Paro', appeared to improve several behavioural and psychological symptoms of general older adult population.
- The effectiveness of Paro, specifically on anxiety for older adults with dementia remains unclear.

What this paper adds

- Paro had the potential to improve anxiety, agitation, depression, medication use, and sociability among older adults with dementia.
- Paro had a very small impact in the total sleep time of older adults with dementia.
- Cost-effectiveness should be further evaluated in future studies to determine if Paro is worthy of investment.

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https://doi.org/10.1016/j.ijnurstu.2023.104530
0020-7489/

1. Introduction

Dementia is a chronic syndrome that progressively deteriorates cognitive function, interfering with one's ability to function independently (Arvanitakis et al., 2019; Duong et al., 2017). Damage to the cerebral cortex causes cognitive impairments due to synaptic failure, changes in cerebral metabolism, or inflammation (Duong et al., 2017). According to the World Health Organisation, more than 55 million people worldwide live with dementia, and this number is expected to increase to 139 million in 2050 (World Health Organization, 2021). Dementia is more prevalent in older adults aged ≥60 years (Cenko et al., 2021). Approximately 50%–90% of people with dementia experience behavioural and psychological symptoms, which are the most common symptoms (Cerejeira et al., 2012; Cloak and Khalili, 2020; Hernandis et al., 2019). These symptoms include a diverse range of emotional, perceptual, and behavioural disturbances, the most prevalent of which are anxiety, agitation, depression, and apathy (Cerejeira et al., 2012; Cloak and Khalili, 2020; Baharudin et al., 2019). These symptoms can lead to negative impacts such as decreased quality of life, increased sleep disorders, social isolation, and worsening dementia (Peters et al., 2015; Zhou et al., 2019). Thus, it is essential to manage these symptoms to promote quality of life among people with dementia.

Non-pharmacological interventions are recommended as first-line treatment for the behavioural and psychological symptoms of dementia as medications may result in serious adverse events. Animal-assisted therapy is one intervention that has been shown to ameliorate symptoms for people with dementia as it reduces loneliness and improves communication, leading to an overall better quality of life (Filan and Llewellyn-Jones, 2006; Rodrigo-Claverol et al., 2020; Yakimicki et al., 2018). However, animal-assisted therapy may not be feasible and safe for everyone due to allergies, fear of animals, costs, and potential injuries through bites and scratches. Owing to the advancement of technology, artificial intelligence systems have been used to promote human health. Recently, animals are being replaced with pet robots to provide similar outcomes as animal-assisted therapy without the added risk of injuries and allergies. Pet robots give users a sense of autonomy and enhance their mental and emotional well-being through sensory stimulations associated with reductions in stress levels, loneliness, and severity of the behavioural and psychological symptoms of dementia (Sicurella and Fitzsimmons, 2016).

There are several types of pet robots; however, this review specifically focused on Paro, as it is widely studied and recognised. Paro is a baby harp seal-like mental commitment therapeutic robot designed in Japan by Shibata in 1993 (Supplementary Fig. 1). Paro has five sensors—tactile, visual, auditory, temperature, and posture (Shibata and Coughlin, 2014). These sensors allow Paro to move its tail and flippers, blink its eyes, and imitate the sound of an actual baby harp seal, making it seem realistic or 'alive' to users (Shibata and Coughlin, 2014). All these functions aim to make it soft, warm, and cuddly to encourage physical contact. In previous studies, Paro reduced the behavioural and psychological symptoms of dementia (Lane et al., 2016; Moyle et al., 2017; Shibata and Coughlin, 2014). Furthermore, it reduced the perception of pain, decreasing the need to take pain-relief medications (Geva et al., 2020; Pu et al., 2020). Paro improved night-time sleep in older adults with dementia, reducing sleep disturbances and increased their social interaction by stimulation (Pu et al., 2021; Šabanović et al., 2013; Shibata, 2012; Takayanagi et al., 2014).

Several reviews evaluated the effects of Paro on older adults (Chang and Sung, 2013; Pu et al., 2019; Wang et al., 2021). One systematic review examined Paro's effect on older adults with dementia, however, no meta-analysis was conducted (Kang et al., 2020), while two reviews included quasi-experimental research (Chang and Sung, 2013; Lu et al., 2021). Another systematic review by Leng et al. (2019) conducted a subgroup analysis for the different categories of behavioural and psychological symptoms of dementia, and it was noted that 'anxiety' and 'apathy' were combined as one subgroup with minimal emphasis and explanation on anxiety. As such, this review further explored anxiety as an independent outcome. Additionally, no existing review conducted a meta-analysis to evaluate the efficacy of Paro on medication use and total sleep time. Hence, this systematic review aims to assess the efficacy of Paro on the behavioural and psychological symptoms of dementia (particularly anxiety), medication use, total sleep time, and sociability in older adults with dementia. Outcomes similar to those reported in existing systematic reviews were reported in this systematic review to strengthen the existing findings (Chang and Sung, 2013; Leng et al., 2019; Lu et al., 2021).

2. Methods

This review was conducted using the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to optimise quality (Page et al., 2021). The protocol was registered in PROSPERO (CRD42022296504).

2.1. Search strategy

A three-step search strategy was conducted by two independent reviewers (NLAR and LY) using nine electronic databases (PubMed, Cochrane, Embase, Medline, Web of Science, Scopus, Institution of Electrical Engineers Xplore, PsycInfo, and ProQuest Dissertations and Theses), ClinicalsTrials.gov, and screening of reference lists of the included studies to search for published, unpublished, and grey literature and ongoing trials. The search period was from January 2003, when Paro (PARO Robots U.S., 2014) was commercialised, to November 2022. The search strategy was validated by a specialist medical librarian. As English is a common language among all authors, only English publications were considered. The key search terms included 'social robot', 'Paro', 'dementia', 'cognitive impairment', and 'older adults'. Further details regarding the key search terms and search strategies of each electronic database are reported in Supplementary Table 1.

2.2. Eligibility criteria

Studies (1) including older adults aged ≥60 years with any form of dementia; (2) using Paro as an intervention; (3) measuring at least one of the following outcomes: anxiety, agitation, depression, apathy, medication use, sociability, and total sleep time; (4) consisting of a control group which received either usual care or active interventions; and (5) that were either randomised controlled, crossover, or cluster-randomised trials reported in English were included. Studies with non-experimental, quasi-experimental, or one-group experimental designs, cohort studies, case–control studies, review or discussion papers, trial protocols, and non-English studies were excluded.

2.3. Selection process

All studies retrieved from the databases search were managed and organised by exporting the citations to EndNote X9. Two independent reviewers (NLAR and LY) selected the studies by removing duplicates and screening the titles and abstracts of the remaining studies based on the eligibility criteria. Discrepancies between the two reviewers were settled by consulting a third reviewer (VXW). Studies that met the eligibility criteria or had insufficient information in the title and abstract were further examined with full-text articles.

2.4. Data extraction

Both the data extraction and risk of bias forms were adapted from the Cochrane Handbook for Systematic Reviews of Interventions and were pilot tested by two reviewers independently on five full-text studies to ensure consistency and relevancy (Higgins and Green, 2011). The two reviewers independently extracted relevant information, including author, year, country, study design, participants' characteristics, intervention frequency and duration, type of comparator, settings, follow-ups, and outcomes measured. The authors of the included studies were contacted via email for additional unpublished information or missing data.

2.5. Risk of bias and quality appraisal

Two reviewers assessed the risk of bias and overall quality of evidence independently, and discrepancies were resolved by discussion with the third reviewer. The risk of bias assessment of all included studies using the Cochrane Risk of Bias Tool was based on sequencing generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective outcome reporting, and other biases (Higgins et al., 2011). Each domain was graded either as high, low, or unclear.

To determine the overall quality of evidence of each outcome, the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework was used and was rated as high, moderate, low, or very low based on the following five domains: overall studies' methodological limitations, inconsistency, indirectness, imprecision, and publication bias (Guyatt et al., 2008). Cohen's Kappa (κ) was calculated to determine the degree of inter-rater agreement, where $\kappa > 0.6$ was acceptable (McHugh, 2012).

2.6. Data synthesis

Review Manager 5.4 was used to manage and extract data from the included studies. All outcomes were reported as continuous data. The standardised mean difference (SMD) was used as the effect measure for continuous data when the included studies assessed the same outcome using different measurement tools (Deeks et al., 2021). If the same measurement tool was used, mean difference was utilised (Deeks et al., 2021). Cohen's definitions were used to interpret the SMD effect size as follows: <0.5 as small, 0.5–0.8 as moderate, and >0.8 as large (Higgins et al., 2021).

Heterogeneity was assessed using the chi-square test and I^2 test. A p-value of <0.1 for the chi-square test indicated considerable heterogeneity. The I^2 test was interpreted as not important (0%–40%), moderate (30%–60%), substantial (50%–90%), or considerable (75%–100%) heterogeneity (Deeks et al., 2021). Sensitivity analysis was conducted if the heterogeneity indicated 'considerable' by removing each study from the pool and comparing the I^2 value before and after removal (Higgins et al., 2021). Subgroup analysis was performed to determine if the efficacy of Paro was influenced by the intervention duration, setting, and stage of dementia and investigate for any high heterogeneity (Higgins et al., 2021). A fixed-effects model was used to analyse the pooled effect size if there were too few studies to acquire an accurate estimate of the between-studies variance (Borenstein et al., 2010). Otherwise, a random-effects model was used.

3. Results

3.1. Study selection

A total of 1243 articles were identified from the databases, and two additional articles were identified through other sources. After removing duplicates, 879 articles were screened for titles and abstracts, and 841 were excluded due to irrelevance. In total, 37 articles were selected for full-text screening, of which 12 articles from eight studies were included in this systematic review. Of the 12 articles, 11 were eligible for meta-analysis, while one was included for narrative synthesis. The detailed search process was illustrated in the PRISMA flow diagram (Fig. 1).

3.2. Characteristics of included studies

Detailed characteristics of the included studies are listed in Table 1. Among the eight studies, three were conducted in Australia, and one each was conducted in Norway, South Korea, New Zealand, Spain, and the United States of America. The sample size across all studies ranged from 18 to 415 participants, and the participants' mean age ranged from 83.3 to 86.8 years. All studies were conducted in aged care facilities, with one study conducted in both day-care centres and participants' homes (Liang et al., 2017). Most participants were female, accounting for at least 55%–100% in each trial arm. The duration of the Paro intervention ranged from 5 to 12 weeks, while the session frequency ranged from twice to five times a week. Each session lasted for 15 to 45 min on average. In the Paro group, the intervention was either facilitated or non-facilitated; the facilitated intervention was conducted by trained facilitators or research assistants. The control treatment included usual care, humanoid robots, dogs, and plush toys. The outcome measures included anxiety, agitation, depression, apathy, medication use, sociability, and total sleep time.

3.3. Risk of bias and quality assessment

Details of the risk of bias assessment of the included studies are shown in Fig. 2. All 12 articles reported detailed methods of random sequence generation and had no evidence of any reporting bias (Jøranson et al., 2020; Jøranson et al., 2016; Jøranson et al., 2015; Koh and Kang, 2018; Liang et al., 2017; Moyle et al., 2018; Moyle et al., 2017; Moyle et al., 2013; Petersen et al., 2017; Pu et al., 2020; Pu et al., 2021; Soler et al., 2015). The calculated overall risk of bias inter-rater reliability was acceptable ($\kappa = 0.82$). There were 10 articles that were either judged as 'high risk' or 'unclear' for performance bias as blinding of participants was often unfeasible (Jøranson et al., 2020; Jøranson et al., 2016; Jøranson et al., 2015; Koh and Kang, 2018; Liang et al., 2017; Moyle et al., 2013; Petersen et al., 2017; Pu et al., 2020; Pu et al., 2021; Soler et al., 2015). Two articles were judged as unclear for detection bias as it was not reported (Petersen et al., 2017; Pu et al., 2021). For attrition bias, eight articles were judged to be of 'low risk' as the studies had a $<20\%$ overall attrition rate, with or without intent-to-treat analysis, and the attrition rates between the intervention and control groups were not significantly different (Jøranson et al., 2015; Jøranson et al., 2016; Koh and Kang, 2018; Liang et al., 2017; Moyle et al., 2017; Moyle et al., 2018; Pu et al., 2020; Pu et al., 2021). Lastly, 3 of the 12 articles were judged to have a 'high risk' of other bias due to the small sample size (Koh and Kang, 2018; Liang et al., 2017; Moyle et al., 2013).

The overall quality of evidence was evaluated using the GRADE framework, and detailed explanations were stated in Supplementary Table 2. The quality of evidence for all outcomes was graded as low due to the methodological limitations, small sample size, and wide confidence intervals (CIs).

3.4. Effects of Paro

The fixed-effect model was utilised to analyse the pooled effect size for all outcomes as there were few studies included in the meta-analysis (Borenstein et al., 2010).

3.4.1. Anxiety

Five studies investigated anxiety symptoms post-intervention, and only four studies were included in the meta-analysis pooling 547 participants (Fig. 3) (Liang et al., 2017; Moyle et al., 2017; Moyle et al., 2013; Petersen et al., 2017; Pu et al., 2020). Results indicated that Paro had a

small effect in reducing anxiety symptoms (SMD: −0.17, 95% CI [−0.35, 0.00]), with low heterogeneity observed across the studies (Chi^2: 5.35, p = 0.25, I^2 = 25%). Three studies used the Ratings for Anxiety in Dementia (RAID) scale (Moyle et al., 2017; Moyle et al., 2013; Petersen et al., 2017; Pu et al., 2020). Moyle et al. (2017) measured anxiety symptoms through video observation, and the data were extracted by trained research assistants using Video Coding Protocol-Incorporating Observed Emotion Scheme. This program allows the research assistants to code observational data in millisecond intervals and convert it into quantitative data (Jones et al., 2015).

As we noted that the largest study (Moyle et al., 2017) had the smallest effect size and used video observation as opposed to self-reported questionnaires (i.e. Ratings for Anxiety in Dementia scale), a subgroup analysis was conducted (post-hoc). While the pooled result from studies using video observation was not significant, there was no significant subgroup difference (Chi^2: 2.98, p = 0.08, I^2 = 66.4%).

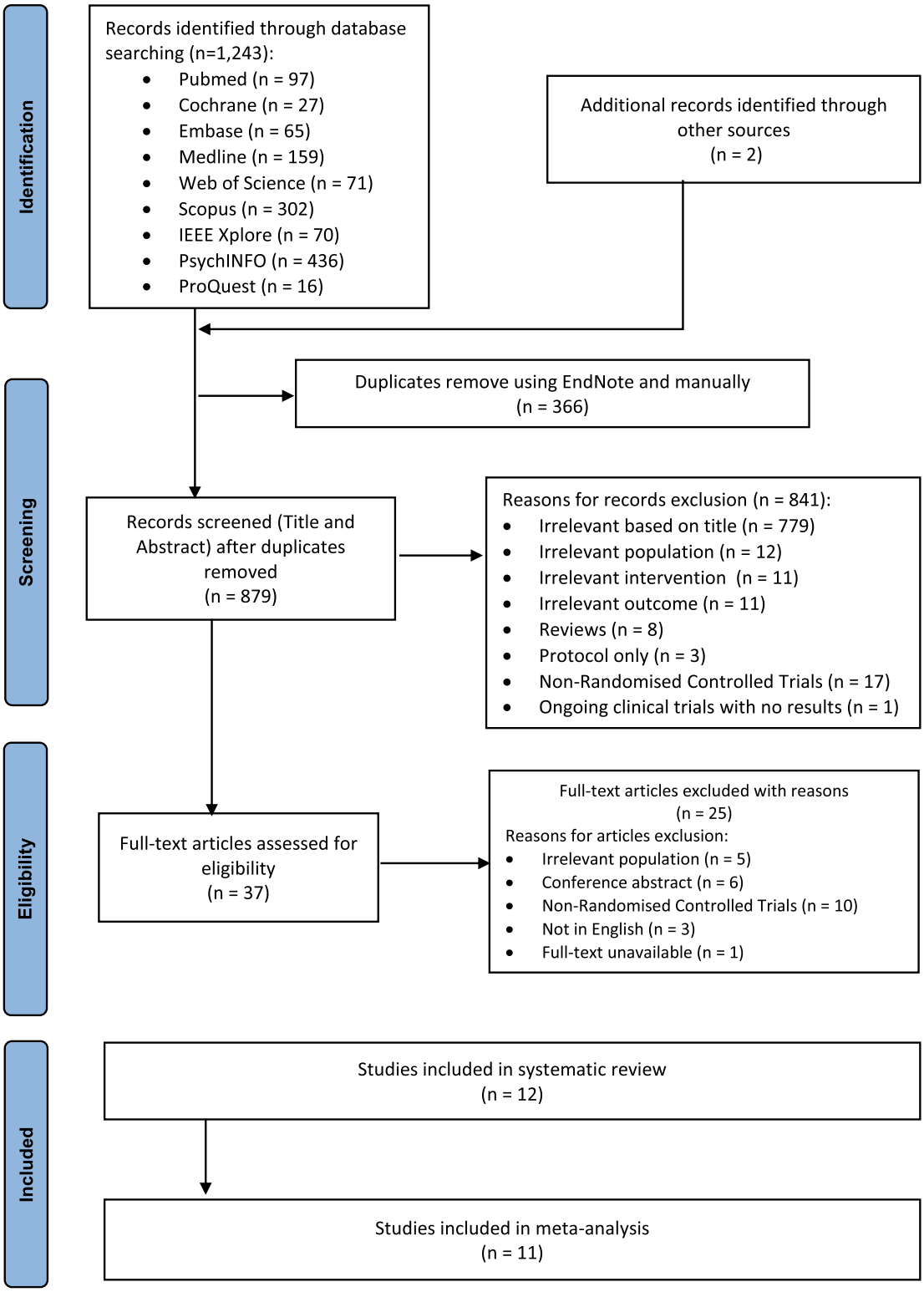

Fig. 1. PRISMA flow diagram.

Thus, it is unclear that the mode of observation affects the results. The questionnaire subgroup had a larger effect in reducing anxiety (SMD: −0.43, 95% CI [−0.77, −0.09]) than the video observation subgroup (SMD: −0.08, 95% CI [−0.28, 0.13]). There was no heterogeneity observed for both the self-reported questionnaires (Chi^2: 1.82, p = 0.40, I^2 = 0%) and video observation (Chi^2: 0.55, p = 0.46, I^2 = 0%) subgroups.

One study was excluded as the authors measured anxiety symptoms by investigating physiological changes in blood pressure (Liang et al., 2017). The authors reported no significant differences in blood pressure following Paro intervention, either across time or between conditions. There were no significant differences observed in anxiety symptoms immediately post-intervention.

3.4.2. Agitation

Five studies assessed the effect of Paro on agitation post-intervention and were included in the meta-analysis (Fig. 4) (Jøranson et al., 2015; Koh and Kang, 2018; Liang et al., 2017; Moyle et al., 2017; Pu et al., 2020). The studies assessed agitation using the Brief Agitation Rating Scale (BARS) (Jøranson et al., 2015), Korean version of the Cohen-Mansfield Agitation Inventory (K-CMAI) (Koh and Kang, 2018), Cohen-Mansfield Agitation Inventory-Short Form (CMAI-SF) (Liang et al., 2017; Moyle et al., 2017; Pu et al., 2020), and video observation (Moyle et al., 2017). The meta-analysis pooled 769 participants and showed that Paro had a small effect on reducing agitation (SMD: −0.27, 95% CI [−0.42, −0.12]). Low heterogeneity was observed across the studies (Chi^2: 9.86, p = 0.20, I^2 = 29%).

Similar to anxiety, subgroup analysis was conducted to compare studies that used self-reported questionnaires (i.e. Brief Agitation Rating Scale and Cohen-Mansfield Agitation Inventory) and Moyle et al.'s (2017) study that used video observation (post-hoc). There was no subgroup difference (Chi^2: 0.42, p = 0.52, I^2 = 0%), making it unclear if the mode of observation affects the results. The video observation subgroup (SMD: −0.22, 95% CI [−0.43, −0.01]) had a slightly smaller effect in reducing agitation than that of the questionnaire subgroup (SMD: −0.32, 95% CI [−0.54, −0.10]). The heterogeneity for the self-reported questionnaires subgroup was moderate (Chi^2: 8.34, p = 0.14, I^2 = 40%), but was not important for the video observation subgroup (Chi^2: 1.10, p = 0.29, I^2 = 9%).

3.4.3. Depression

Five studies assessed depression and were included in the meta-analysis pooling 217 participants using the fixed-effect model (Fig. 5) (Jøranson et al., 2015; Liang et al., 2017; Moyle et al., 2013; Petersen et al., 2017; Pu et al., 2020). Four studies used the Cornell Scale for Symptoms of Depression in Dementia (Jøranson et al., 2015; Liang et al., 2017; Petersen et al., 2017; Pu et al., 2020). Moyle et al. (2013) used the Geriatric Depression Scale. The Paro group was found to exhibit a small effect on reducing depression compared to the control group (SMD: −0.40, 95% CI [−0.68, −0.13]). Moderate heterogeneity was observed across the studies (Chi^2: 7.03, p = 0.13, I^2 = 43%).

3.4.4. Medication use

Four studies assessed medication use among older adults with dementia but only three were included in the meta-analysis (Supplementary Fig. 2) (Liang et al., 2017; Jøranson et al., 2016; Petersen et al., 2017; Pu et al., 2020). The meta-analysis pooled 157 participants and indicated a moderate effect in decreasing medication use (SMD: −0.63, 95% CI [−0.88, −0.38]). Heterogeneity tests indicated no heterogeneity across the study (Chi^2: 2.89, p = 0.72, I^2 = 0%). Petersen et al. (2017) also assessed the use of depression and sleep medication. While the Paro group had a decrease in the use of both medications, there were no changes seen in the control group. One study was excluded as the author assessed medication use as a categorical variable (Liang et al., 2017). There was also no change in medication use in both the Paro and control groups from baseline to immediate post-intervention (Liang et al., 2017).

3.4.5. Total sleep time

Three studies investigated total sleep time and were included in the meta-analysis (Supplementary Fig. 3) (Jøranson et al., 2020; Moyle et al., 2018; Pu et al., 2021). The meta-analysis pooled 255 participants with a very small effect on the total sleep time (SMD: −012, 95% CI [−0.29, 0.05]). Low heterogeneity was observed across the studies (Chi^2: 6.77, p = 0.34, I^2 = 11%).

3.4.6. Narrative synthesis for Paro on apathy and sociability

Despite apathy being one of the most common behavioural and psychological symptoms of dementia, only two studies measured apathy (Moyle et al., 2013; Soler et al., 2015). Hence, a meta-analysis was not conducted. Moyle et al. (2013) measured apathy using the Apathy Evaluation Scale, while Soler et al. (2015) used the Apathy Scale for Institutionalised Patients with Dementia Nursing Home version. Moyle et al. (2013) conducted a randomised crossover trial in which participants were exposed to Paro before a 3-week washout period. Meanwhile, Soler et al. (2015) conducted two experimental phases in a nursing home. In the first phase, the participants in the Paro group were compared to the participants in the NAO (a humanoid social robot) group and a usual care group. In the second phase, the participants in the Paro group were compared to those in a control group and a group exposed to a real-life dog. In both studies, the authors concluded that Paro was beneficial as there was a statistically significant drop in apathy symptoms, except at the second phase in Soler et al. (2015).

Three studies measured sociability by exposure to Paro (Koh and Kang, 2018; Liang et al., 2017; Moyle et al., 2017). Unfortunately, one study had no outcome data for the control group, resulting in insufficient studies to conduct a meaningful meta-analysis (Koh and Kang, 2018). Koh and Kang (2018) measured sociability through direct observation conducted by the trained research assistants independently. They evaluated the observations using a table developed by Wada et al. (2010). Liang et al. (2017) measured sociability by observation, with one of the researchers using the time sampling method throughout the interaction period. Moyle et al. (2017) recorded video observations of the participants, and the data were extracted by trained research assistants using the Video Coding Protocol-Incorporating Observed Emotion Scheme to measure sociability. All these studies reported that there was a significant positive increase in social interactions as participants in the Paro group were more verbally and visually engaged with Paro.

4. Discussion

The results of this review showed that Paro had a moderate effect on medication use and a small effect on anxiety, agitation, and depression. However, a very small effect was found on total sleep time favouring controls. This meta-analysis showed that Paro reduced anxiety with a small effect size. One possible explanation is that Paro emphasises physical contact, which stimulates the human brain (Shibata, 2012). Humans can perceive if a physical touch with either a person or an object is positive or negative (Eckstein et al., 2020; Hertenstein et al., 2009). If a physical touch is deemed to be positive, hormones such as dopamine, serotonin, and oxytocin that play a positive role in enhancing the human mood are released (Young et al., 2020). Furthermore, positive physical touch reduces the level of cortisol, a hormone associated with stress (Young et al., 2020). Evidently, Paro was able to reduce cortisol levels and increase oxytocin in older adults living in a care facility (Wada and Shibata, 2007).

Furthermore, anxiety causes the sympathetic branch of the autonomic nervous system to be activated, resulting in physiological changes such as increased heart rate and blood pressure (Jimeno et al.,

Table 1
Characteristic of included studies.

Author (year), country	Study design	Participants sample size (Female %)	Mean age (SD)	Dementia definition used	Intervention/single or group format/facilitated or non-facilitated	Control	Setting	Frequency and duration of intervention	Follow-ups	Outcome measured (tools used)
Jøranson et al. (2015), Norway [42]	Cluster RCT	IG: 27 (70%) CG: 26 (63.3%)	IG: 83.9 (7.2) CG: 84.1 (6.7)	Norwegian version of the MMSE	Paro/group/facilitated	Usual care	Nursing home	Twice per week, 30 min/session, for 12 weeks	Baseline, post-intervention, 12-weeks post-intervention	• Agitation (BARS) • Depression (CSDD)
Jøranson et al. (2016), Norway [43]	Cluster RCT	IG: 27 (70%) CG: 26 (63.3%)	IG: 83.9 (7.2) CG: 84.1 (6.7)	Norwegian version of the MMSE	Paro/group/facilitated	Usual care	Nursing home	Twice per week, 30 min/session, for 12 weeks	Baseline, post-intervention, 12-weeks post-intervention	• Medication usage of analgesics, antipsychotics, anxiolytics, sedatives (ATC Classification Usage) • Quality of life (QUALID)
Jøranson et al. (2020), Norway [47]	Cluster RCT	IG: 27 (70%) CG: 27 (63%)	IG: 83.9 (7.2) CG: 85.2 (6.73)	Norwegian version of the MMSE	Paro/group/facilitated	Usual care	Nursing home	Twice per week, 30 min/session, for 12 weeks	Baseline, post-intervention, 12-weeks post-intervention	• SE % (Actigraphy) • WASO (Actigraphy) • NA > 5 (Actigraphy) • TST (Actigraphy)
Koh and Kang (2018), South Korea [44]	RCT	IG: 17 (100%) CG: 16 (93.7%)	IG: 86.8 (6.42) CG: 86.2 (5.72)	MMSE-K	Paro/group/facilitated	Usual care	Long term care facility	Twice per week, 30 min/session, for 6 weeks	Baseline, post-intervention	• Agitation (K-CMAI) • Cognitive Function (MMSE-K) • Social Interaction (Observation) • Emotion (AER)
Liang et al. (2017), New Zealand [40]	Pilot RCT	Total: 24 (64% F) IG: 13 (NA) CG: 11 (NA)	Total: NA 67–98 years	Formal diagnosis	Day care centres: Paro/group/facilitated Participants' homes: Paro/individual/non-facilitated	Usual care	Two dementia day care centres and participant's homes	Two to three times per week, 30 min/session, for 6 weeks	Baseline, post-intervention, 6-weeks post-intervention	• Agitation (CMAI-SF) • Depression (CSDD) • Medication usage of dementia-related meds • Cognitive function (Addednbrooke's Cognitive Examination) • Neuropsychiatric (NPI-Q) • Stress & anxiety (hair cortisol, blood pressure, heart rate)
Moyle et al. (2013), Australia [46]	Pilot randomised crossover trial	IG: 9 (NA) CG: 9 (NA)	Total: 85.3 (8.4)	DSM 4th edition	Paro/group/facilitated	Interactive reading	One residential care facility	Thrice per week, 45 min/session, for 5 weeks	Baseline, post-intervention	• Depression (GDS) • Quality of life (QOL-AD) • Anxiety (RAID) • Mood states (OERS) • Apathy (AES) • Behaviour (AWS)
Moyle et al. (2017), Australia [18]	Parallel 3-group cluster RCT	IG: 138 (74%) CG (plush toy): 140 (81%) CG (usual care): 137 (72%)	IG: 84 (8.4) CG (plush toy): 86 (7.6) CG (usual care): 85 (7.1)	Formal diagnosis	Paro/individual/non-facilitated	Plush toy and usual care	28 long-term care facilities	Thrice per week, 15 min/session, for 10 weeks	Baseline, post-intervention	• Levels of engagement (video observation) • Mood states (video observation) • Agitation (CMAI-SF)
Moyle et al. (2018), Australia [45]	Parallel 3-group cluster RCT	Daytime: IG: 67 (79%) CG (plush toy): 55 (76%)	Daytime: IG: 84 (8.8) CG (plush	Formal diagnosis	Paro/individual/non-facilitated	Plush toy and usual care	28 long-term care facilities	Thrice per week, 15 min/session, for 10 weeks	Baseline, 5-weeks mid-intervention Post-intervention, 5-weeks post-intervention	• Motor activity (triaxial accelerometer) ○ Step count ○ Physical activity ○ Lying down

		CG (usual care): 53 (66%) Nighttime: IG: 98 (78%) CG (plush toy): 95 (80%) CG (usual care): 87 (67%)	toy): 86 (7.6) CG (usual care): 85 (6.9) Nighttime: IG: 85 (8.3) CG (plush toy): 87 (7.0) CG (usual care): 85 (7.1)							• Sleep patterns (triaxial accelerometer) ○ Total sleep hours daytime and nighttime
Petersen et al. (2017), USA [41]	Randomised block design	IG: 35 (77.1%) CG: 26 (76.1%)	IG: 83.5 (5.8) CG: 83.3 (6.0)	Formal diagnosis and DSM	Paro/group/facilitated	Usual care	Dementia units	Thrice per week, 20 min/session for 12 weeks	Baseline, Post-intervention	• Anxiety (RAID) • Depression (CSDD) • Cognitive function (Global Deterioration Scale) Medication Usage of sedatives, depression, analgesics, and behaviour medication • Arousal state (Galvanic Skin Response) • Stress and anxiety (pulse rate and pulse oximetry)
Pu et al. (2020), Australia [20]	Pilot RCT	IG: 21 (85.7%) CG: 22 (55.4%)	IG: 86.48 (8.81) CG: 85.55 (5.80)	Formal diagnosis and MMSE	Paro/individual/non-facilitated	Usual care	3 long-term care facilities	Five times per week/30 min/session for 6 weeks	Baseline, post-intervention	• Agitation (CMAI-SF) • Depression (CSDD) • Anxiety (RAID) • Medication usage of for PRN medication and scheduled medications
Pu et al. (2021), Australia [21]	Pilot RCT	IG: 21 (85.7%) CG: 20 (55%)	IG: 86.48 (8.81) CG: 85.5 (6.02)	Formal diagnosis and MMSE	Paro/individual/non-facilitated	Usual care	3 long-term care facilities	Five times per week/30 min/session for 6 weeks	Baseline, post-intervention	• Sleep pattern (Actigraphy) ○ Time spent lying down, awake, sleep time • Motor activity (Actigraphy) ○ Skin temperature, distance walked, number of steps taken, time spent in physical activity, energy expenditure
Soler et al. (2015), Spain [48]	Randomised block design	Total phase 1: 101 (88%) Total phase 2: 110 (90%) IG phase 1: 33 (NA) IG phase 2: 42 (NA) CG phase 1: 30 (NA) CG phase 2: 32 (NA)	Total phase 1: 84.68 (NA) Total phase 2: 84.7 (NA)	Formal diagnosis	Paro/group/facilitated	Usual care NAO Dog	Nursing home	Twice per week, 30 to 40 min/session for 12 weeks	Baseline, post-intervention	• Quality of life (QUALID) • Cognitive function (MMSE, sMMSE, and Global Deterioration Scale) • Apathy (APADEM-NH and AI) • Neuropsychiatric (NPI-Q)

Abbreviations: AER, Apparent Emotion Rating; AES, Apathy Evaluation Scale; AI, Apathy Inventory; APADEM-NH, Apathy Scale for Institutionalised Patients with Dementia Nursing Home version; ATC, Anatomical Therapeutic Chemical; AWS, Algase Wandering Scale; BARS, Brief Agitation Rating Scale; CG, Control Group; CMAI, Cohen-Mansfield Agitation Inventory; CMAI-SF, Cohen-Mansfield Agitation Inventory Short Form; CSDD, Cornell Scale for Symptoms of Depression in Dementia; DSM, Diagnostic and Statistical Manual of Mental Disorders Diagnostic; GDS, Geriatric Depression Scale; IG, Intervention Group; MMSE, K-CMAI, Korean version Cohen-Mansfield Agitation Inventory; Mini-Mental State Examination; MMSE-K, Korean Mini-Mental State Examination; NA > 5, Number of Awakenings longer than 5 min; NPI-Q, Neuropsychiatric Inventory Brief Questionnaire Form; OERS, Observed Emotion Rating Scale; PRN, pro re nata (i.e. when necessary); QOL-AD, Quality of Life in Alzheimer's Disease Scale; QUALID, Quality of Life in Late-Stage Dementia; RAID, Rating Anxiety in Dementia Scale; SE %, Sleep Efficiency Percentage; sMMSE, Severe Mini Mental State Examination; TST, Total Sleep Time; WASO, Wake after sleep onset.

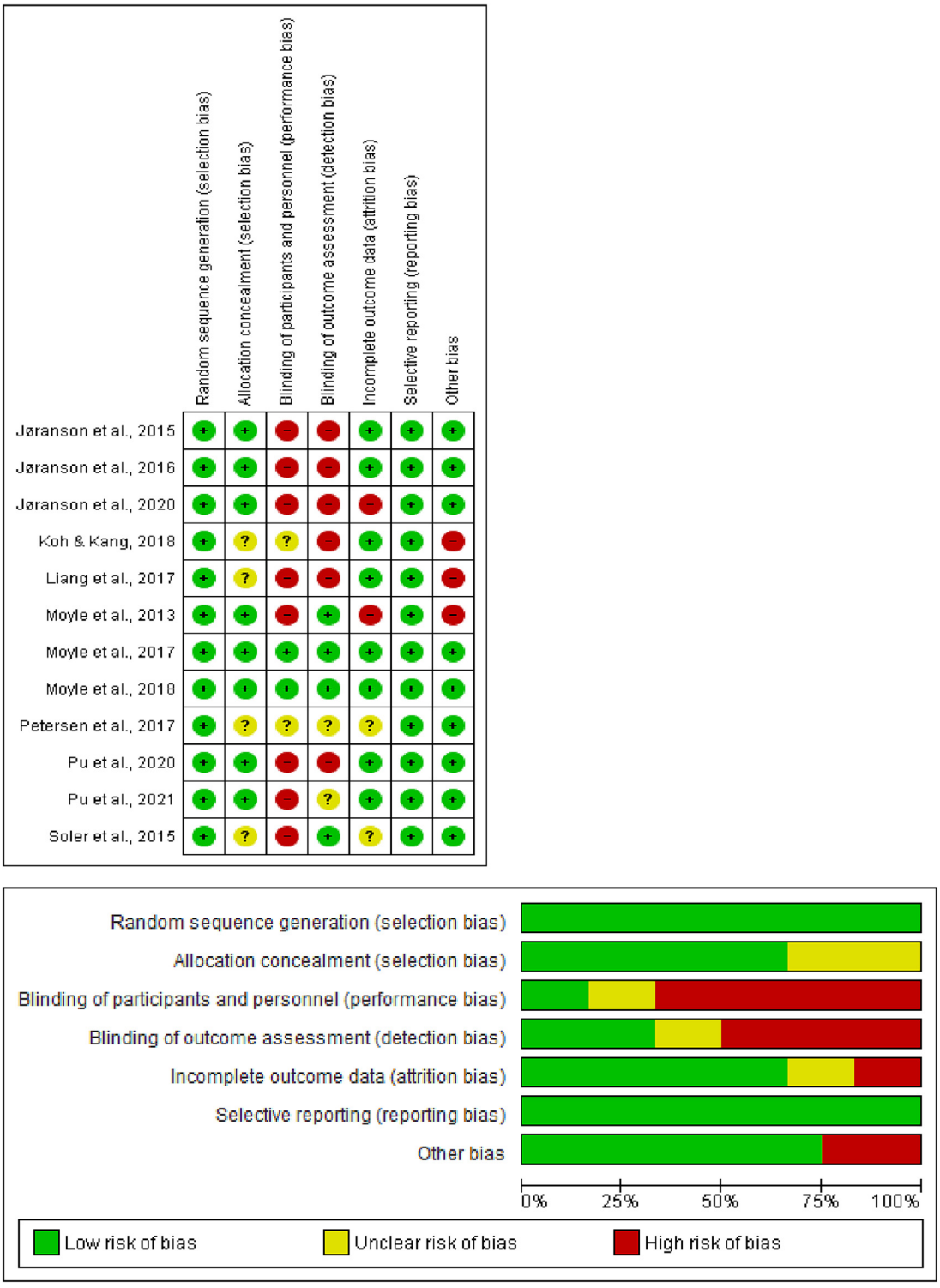

Fig. 2. Risk of bias assessment summary of included studies.

2011). Increased oxytocin levels can reverse these effects (Jankowski et al., 2020). Two of the included studies reported that Paro decreased blood pressure and heart rate compared to baseline values (Liang et al., 2017; Petersen et al., 2017). Similarly, another study by Robinson et al. (2013) concluded that Paro reduced blood pressure in older adults. Therefore, the interaction between humans and artificial objects such as Paro can have a calming effect through these hormonal and physiological changes, decreasing anxiety (Eckstein et al., 2020).

Loneliness and social isolation in people with dementia are associated with anxiety and depression (Center for Disease Control and Prevention, 2021; Victor et al., 2020). As Paro was designed to mimic a living animal, results from animal-assisted therapy could explain the positive results towards improving anxiety. Animal-assisted therapy can offer companionship to reduce loneliness and provide a source of motivation, pleasure, and relaxation (Lai et al., 2019). Thus, Paro acts as a form of companionship that allows recipients to interact with and care for, reducing loneliness and, in turn, decreasing anxiety.

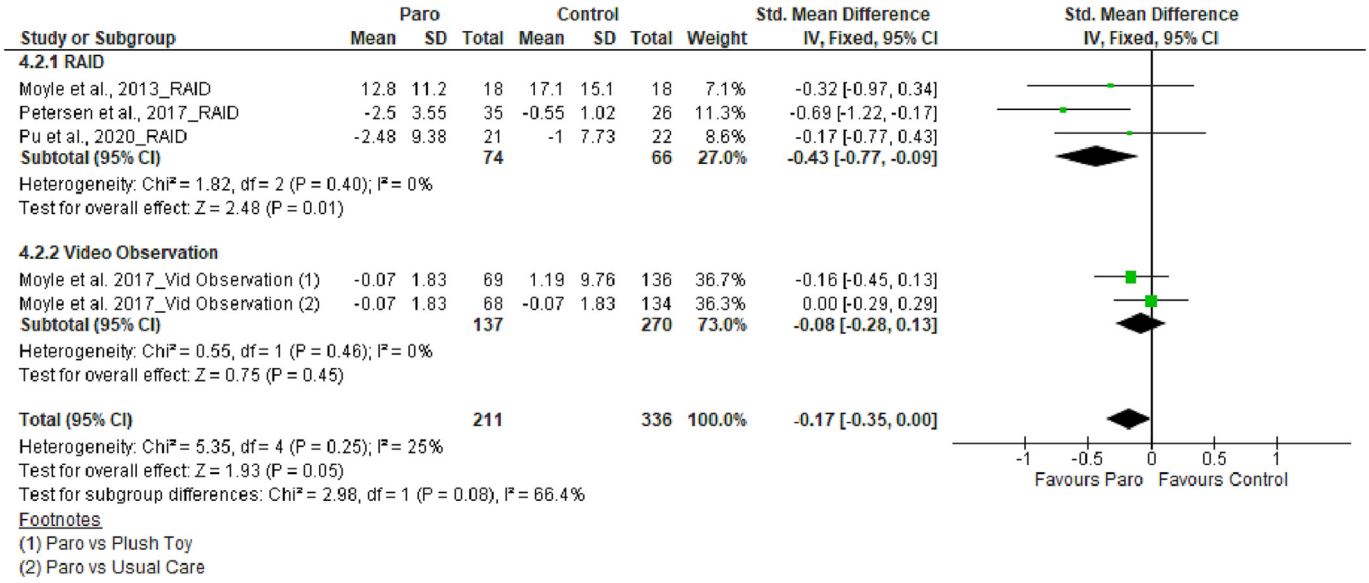

Fig. 3. Forest plot of the effect of Paro on anxiety.

Our findings suggested that Paro had a small effect on both agitation and depression, which were consistent with Leng et al.'s (2019). Our meta-analysis included an additional study further strengthening the evidence that Paro can reduce agitation and depression symptoms. However, our results were inconsistent with the results of Lu et al. (2021). One plausible reason for the inconsistency is that our review analysed the effect of Paro immediately post-intervention, while Lu et al. (2021) analysed it at different time points. The beneficial effects on agitation, depression, and apathy can be explained by similar reasons as were mentioned earlier for anxiety. For example, Paro reduces cortisol levels, which reduces stress levels, and hence, the severity of the behavioural and psychological symptoms of dementia is reduced as well (Kwon and Cho, 2019; Wada and Shibata, 2007).

This meta-analysis also indicated that Paro had a moderate effect on reducing medication use. Paro reduced psychotropic, behavioural, and analgesic medication in all the included studies (Jøranson et al., 2016; Petersen et al., 2017; Pu et al., 2020). Since Paro ameliorated anxiety, agitation, depression, and apathy, as explained earlier, the need for psychotropic and behavioural medication would be reduced. Furthermore, interacting with Paro could be a form of distraction from negative emotions and pain. Distraction is an effective method for alleviating pain as it induces an analgesic effect through the rivalry of the distraction and pain stimulus (Demange et al., 2019). Thus, the use of analgesics would decrease. As medication usage decreases, its side effects also reduce, promoting better mood in older adults with dementia. For example, fluoxetine is an antidepressant drug which may cause diarrhoea, dry mouth, nausea, or insomnia (Sohel et al., 2022). Hence, older adults

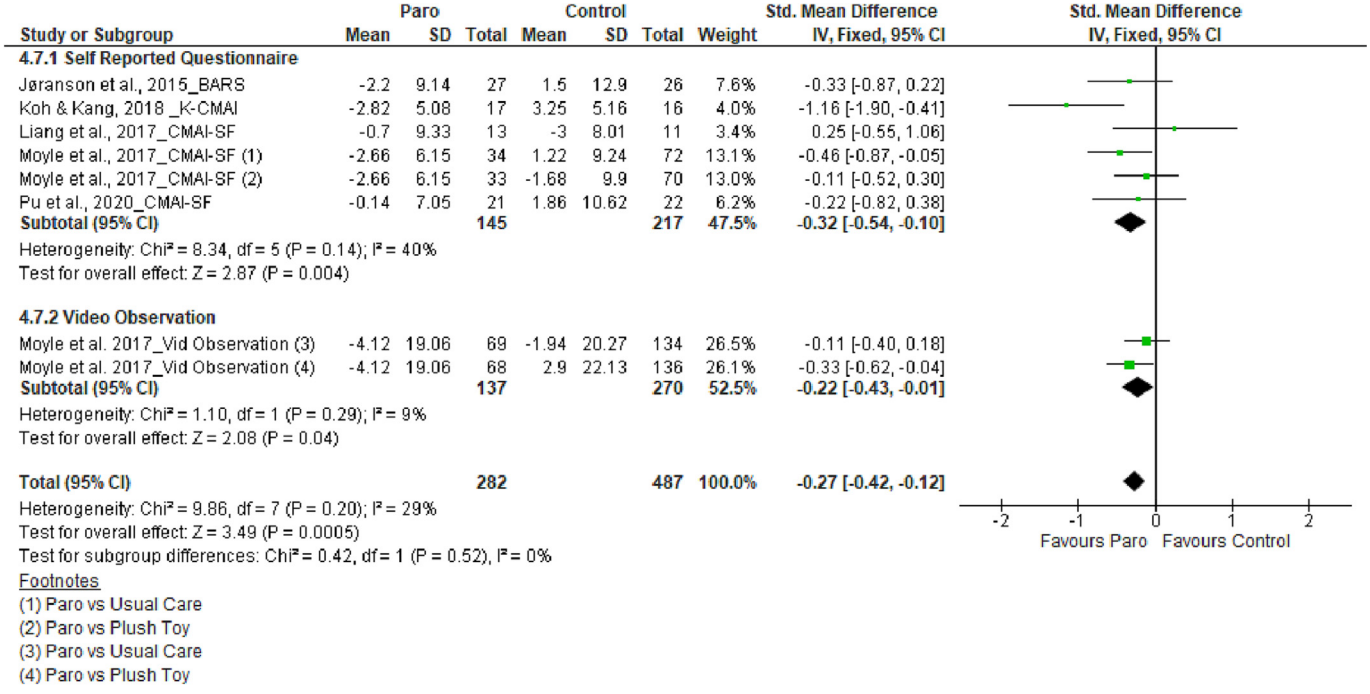

Fig. 4. Forest plot of the effect of Paro on agitation.

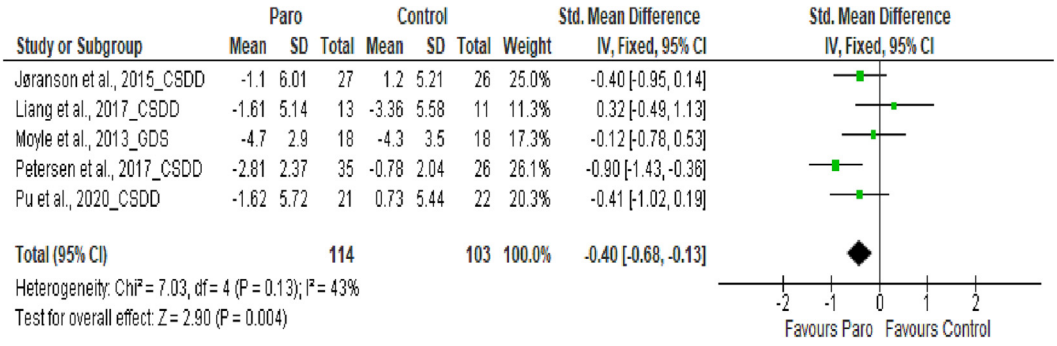

Fig. 5. Forest plot of the effect of Paro on depression.

with dementia may avoid these side effects when there is reduction in medication use.

There was a very small effect on total sleep time, favouring the control group. One possible reason for the insignificant difference was reported by two studies, stating that the armband given to the participants to assess sleep patterns and motor activity was not well tolerated, especially at night (Moyle et al., 2018; Pu et al., 2021). This may lead to inaccuracy of data on total sleep time. Thus, the results of this outcome should be interpreted with caution. Moreover, the participants in the included studies either lived in nursing homes or facilities, and the residents often spent time mostly in their rooms or in bed instead of engaging in structured social activities (Jøranson et al., 2020; Donovan et al., 2014). Thus, participants reduced their nap frequency while engaging with Paro; this could possibly explain why the total sleep time was reduced in the Paro group.

Paro improved sociability in all the included studies (Koh and Kang, 2018; Liang et al., 2017; Moyle et al., 2017). Consistent with our findings, McGlynn et al. (2017) reported that Paro provided emotional support and a sense of belonging for healthy older adults living in aged care facilities. Paro can increase social interaction between people by providing them with the opportunity to express positive emotions through physical contact (Koh and Kang, 2018). Paro also served as a social stimulus that led to increased communication (Takayanagi et al., 2014). Furthermore, people with dementia experiencing depressive symptoms are significantly more likely to experience social isolation (Shub et al., 2011), thus explaining how Paro improves sociability by decreasing depressive symptoms.

4.1. Strengths and limitations

This review applied the comprehensive three-step search strategy and used nine electronic databases. Furthermore, it only included studies with rigorous study designs. However, it has some limitations. First, only English articles were included, which may result in publication bias. Second, the sample size of the included studies was relatively small, which might be insufficient in generally representing older adults with dementia (Lin, 2018). Third, the variation across the approaches (i.e. group and individual interventions, facilitated and non-facilitated) made it difficult to determine which interventional approach is optimal for producing the beneficial effects of Paro. Finally, this review originally planned to use sociability as the primary outcome. Sociability is an important aspect, as older adults with dementia tend not to socialise with others and are most often seen to be alone (Social Care Institute for Excellence, 2020). This would result in older adults being withdrawn and feeling lonely, which is associated with poorer executive function (Salinas et al., 2022). However, after completing the data extraction, we found out that sociability was not a viable option for a feasible meta-analysis. As such, we amended our PROSPERO registration to focus on the behavioural and psychological symptoms of dementia as the primary outcome, specifically anxiety. Although we have changed the primary outcome, sociability was not omitted and was discussed in the narrative synthesis.

4.2. Implications for practice and research

Although Paro has benefits for older adults with dementia, its cost-effectiveness remains unclear. Due to the advanced technology used to develop Paro, a single Paro, excluding the cost of maintenance and supervision for facilitated sessions, may cost up to USD 6000 (Paro Therapeutic Robot, 2022). Mervin et al. (2018) conducted a cost-effectiveness analysis on the cluster-randomised trial (Moyle et al., 2018; Moyle et al., 2017; Moyle et al., 2016). It was concluded that Paro was not cost-effective in reducing agitation as it did not reduce agitation in the study (Mervin et al., 2018). In improving agitation specifically, a plush toy offers greater monetary value than Paro (Mervin et al., 2018). However, the cost-effectiveness of Paro is inconclusive due to the limited studies available. Therefore, further cost-effectiveness analyses should be conducted to determine whether Paro is worth the investment for older adults with dementia to alleviate the behavioural and psychological symptoms, increase sociability, and decrease medication use.

With limited rigorous quality studies, there is a need for more randomised controlled trials with a larger sample size to investigate the beneficial effects of Paro on older adults with dementia; hence, definitive conclusions on the outcomes can be acquired. Future research could focus on determining which interventional approach (i.e. group and individual interventions, facilitated and non-facilitated) is most effective in producing the optimal benefits of Paro. Additionally, as most studies were conducted in aged care facilities, future studies should examine the use of Paro in the community, which would provide beneficial implications for practice. Lastly, as seen above, the subgroup analysis measuring anxiety showed a difference in effect sizes between the self-questionnaire and video observation groups. There are a number of plausible reasons, one of which is that participants' awareness of the video observation may result in behavioural changes. Another reason could be that the self-reported questionnaires detect the subjective feelings better than the observation method. However, the subgroup analysis measuring agitation showed no subgroup difference, with video observation subgroup having only a slightly smaller effect in reducing agitation compared to the questionnaire subgroup. Thus, future research could explore the usefulness of employing both observation and self-reported questionnaires to determine the most effective way of capturing outcomes such as anxiety and agitation.

5. Conclusion and implications

This meta-analysis provides evidence that Paro may be an effective and suitable tool in improving behavioural and psychological symptoms of dementia, sociability, and reducing medication use. However, the potential beneficial effect on total sleep time remains unclear. Additionally, the findings should be interpreted cautiously due to the limited studies

available. Further studies with a rigorous design and a larger sample size are required to determine the optimal approach to using Paro and to fully understand its effectiveness in older adults with dementia.

Summary of the article

Paro is a pet-robot therapy that is able to improve behavioural and psychological symptoms of dementia (BPSD), increase sociability, and reduce medication usage in older adults with dementia.

CRediT authorship contribution statement

Nur Lidiya Abdul Rashid: Writing – review & editing, Writing – original draft, Visualization, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Yihong Leow:** Writing – review & editing, Visualization, Validation, Software, Project administration, Formal analysis, Data curation. **Piyanee Klainin-Yobas:** Writing – review & editing, Visualization, Validation, Methodology, Formal analysis. **Sakiko Itoh:** Writing – review & editing, Visualization, Validation, Methodology, Formal analysis. **Vivien Xi Wu:** Writing – review & editing, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

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.

Acknowledgments

We would like to thank the generous support from Alice Lee Centre for Nursing Studies, Yong Loo Lin School of Medicine, National University of Singapore.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2023.104530.

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