Commentary

Robotic Pets Versus Live Animal-Assisted Therapy for Agitation in Dementia: A Comparative-Effectiveness and Implementation Framework

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Behavioural and psychological symptoms of dementia (BPSD), including agitation, aggression, anxiety, depressed mood, hallucinations, and sleep disturbance, affect up to 90% of people living with dementia and contribute significantly to caregiver burden and the need for institutional care [1,2]. These disturbances can manifest in the early stages of dementia (e.g., subjective cognitive decline, mild cognitive impairment), highlighting that BPSD are not phenomena exclusive to advanced stages [3,4]. Clinical practice guidelines consistently recommend non-pharmacological approaches as the first line of treatment, reserving medication for cases of severe distress or imminent risk [5]. When pharmacotherapy is used, the average benefits are modest and are offset by adverse effects. In a network meta-analysis of 17 randomized trials, compared with placebo, risperidone reduced agitation in participants with BPSD [as measured by the Cohen-Mansfield Agitation Inventory (CMAI)] with a small effect size (standardized mean difference [SMD] −0.26, 95% CI, −0.37 to −0.15), as did aripiprazole (SMD −0.30, 95% CI, −0.55 to −0.05); risperidone and olanzapine increased the incidences of cerebrovascular adverse events (odds ratio [OR] 3.85, 95% CI, 1.55 to 9.55 and OR 4.28, 95% CI, 1.26 to 14.56, respectively), and risperidone also increased extrapyramidal symptoms (OR 2.23, 95% CI, 1.56 to 3.18) [1]. A network meta-analysis of 12 randomized controlled trials (RCTs) revealed that citalopram improved agitation (as measured by the CMAI) in participants with BPSD, with a small effect size (SMD −0.44, 95% CI, −0.72 to −0.16) [6]. Furthermore, short-term trials may underestimate burdens observed in real-world clinical practice, such as metabolic effects (e.g., weight gain, dysglycemia), falls, and neurologic risks. This risk-benefit profile reinforces the case for effective, scalable, and low-risk non-pharmacological interventions.

First-line non-pharmacological treatments for BPSD include music therapy, reminiscence therapy, cognitive stimulation, structured exercise, sensory and environmental therapies, and animal-based interventions, some of which are recommended by clinical guidelines [5]. From an implementation perspective, animal-based interventions are particularly

informative because similar treatments can be applied through either live animal-assisted therapy (AAT) or pet-robot therapy (PRT). These modalities differ significantly in terms of cost, infection-control requirements, and scalability, but all appear to produce similar symptom improvements. This allows for a clinically meaningful comparison of two potentially interchangeable approaches, rather than comparing fundamentally different interventions such as music therapy and exercise.

AAT, using live animals, is attractive, but its large-scale implementation in long-term care (LTC) facilities or hospital geriatric settings is limited by issues such as infection and allergy control policies, uneven access to animals and trained caregivers, and issues related to treatment consistency and scheduling [7,8]. Despite encouraging evidence for AAT in the treatment of dementia, uncertainties remain. A Cochrane systematic review concluded that AAT may slightly alleviate depressive symptoms in patients with dementia (mean difference [MD] −2.87, 95% CI, −5.24 to −0.50; 2 studies, n = 83), but its effect on agitation and other behavioural and psychological symptoms (BPS) in patients with dementia was inconsistent, and the overall certainty of evidence was low [7].

PRT offers a parallel and potentially more easily implemented approach. Evidence for robotic companion animals is growing, particularly in the area of agitation in dementia, but remains constrained by methodological limitations, including challenges in blinding and heterogeneity (e.g., equipment, dosage, outcome measurement) [9–11]. In trials conducted in LTC facilities, staff-led delivery appears feasible. A commonly studied example is the robotic seal comPAnion RObot (PARO), which has been evaluated in cluster-randomized trials and in syntheses incorporating psychosocial and behavioural outcomes [9–12].

Decision-related questions should be comparative. A network meta-analysis of 19 RCTs found that PRT reduced agitation symptoms in patients with BPSD compared to controls (SMD −0.37, 95% CI, −0.72 to −0.01), and there were no significant differences between AAT and PRT in terms of agitation, depression, cognition, or quality of life [13]. These findings redefine the problem: if the average symptom changes between AAT and PRT are similar, then feasibility, reach, sustainability, safety, and ethics become the decisive factors.

However, non-inferiority based solely on a single agitation endpoint is insufficient to justify the use of robotic pets. Unlike medications, the value of PRT is multidimensional and unlikely to depend on any single clinical outcome. Instead, non-inferiority is best understood as one component of a broader comparative-effectiveness and implementation assessment, serving to answer questions that traditional superiority trials (i.e., superiority versus control) cannot: does replacing live animals with a potentially less costly and more scalable modality sacrifice symptom improvement? Traditional superiority designs, which ask whether PRT is superior to a passive control group, do not answer the substitution question because they never place PRT and AAT in the same trial. Non-

inferiority designs, on the other hand, ask whether PRT is inferior to AAT in agitation beyond a certain pre-specified threshold. This is important because it sets a clinical baseline upon which further analyses involving other factors (e.g., depressive symptoms, social engagement, patient preferences, staff workload, infection control, cost, sustainability) can be conducted. Therefore, non-inferiority and comparative-effectiveness are complementary rather than competing designs. The trial outlined below embeds the non-inferiority comparison into a comparative-effectiveness assessment.

This leads to a testable hypothesis: for participants with a neurocognitive disorder and clinically significant agitation, PRT is non-inferior to AAT in reducing agitation over 12 weeks (for example), and may have advantages in reach, consistency of delivery, staff time per session, cost, and safety [13,14]. We believe that the shared benefits of both approaches largely stem from structured engagement, sensory soothing, and the promotion of social interaction. However, this shared-mechanism assumption is provisional. Live animals possess some characteristics that robots can only partially imitate (e.g., spontaneous behaviour, tactile warmth, reciprocal interaction). Whether these characteristics independently influence clinical outcomes remains unclear. This uncertainty requires direct comparative studies (i.e., head-to-head trials). If replacing AAT with PRT produces clinically meaningful changes, then modality-specific characteristics may play a role and can be explored in future research.

The application of this framework extends beyond the realm of agitation. Because BPSD spans anxiety, depression, aggression, sleep disturbance, and social withdrawal, PRT could prove non-inferior for agitation yet differ from AAT in other domains, and clinicians may want to know where each modality performs similarly, where it performs less well, and where it may have unique advantages. For example, using the depression domain, a meta-analysis of older adults found that animal-assisted therapy (AAT) was associated with a reduction in depressive symptoms compared with control conditions (Hedges g −0.72, 95% CI −1.13 to −0.31), whereas pet-robot interventions did not demonstrate a statistically clear benefit [15]. Hedges g is an SMD used when studies assess the same outcome using different measurement scales; it expresses the difference between intervention and comparison groups in relation to the variability of outcomes and includes an adjustment for small-sample bias. As a general statistical convention, an absolute SMD of approximately 0.2, 0.5, and 0.8 may be described as small, moderate, and large, respectively; however, these thresholds are only guides and do not by themselves establish whether an effect is clinically important. Thus, an effect of −0.72 suggests a moderate-to-large difference in depressive symptom scores at the group level, but its clinical significance for an individual older adult depends on factors such as baseline severity, the measurement instrument used, the minimal clinically important difference, and the certainty and

limitations of the underlying evidence [16,17]. A recent network meta-analysis (20 RCTs, 1073 participants) reported the same pattern: live AAT produced the largest reduction in depressive symptoms versus passive control (SMD −2.04, 95% CI, −3.03 to −1.04), while robotic pets had no significant effect (SMD −1.21, 95% CI, −2.79 to 0.38); notably, AAT combined with structured walking (gait training) produced the largest observed effect (SMD −4.82, 95% CI, −6.69 to −2.95) [18]. One explanation is that some AAT protocols also promote mild physical activity or functional engagement, which may help improve mood [19,20]. Animal-related activities (including AAT and pet ownership) have also been proposed as a component of suicide-prevention strategies through social connectedness, although the evidence is still preliminary and should not be interpreted as causation [21]. Because comparative effects may vary across BPSD domains, non-inferiority on agitation should not be assumed to imply equivalence more broadly (i.e., across other BPSD domains). Agitation should therefore remain the primary endpoint, with depression, quality of life, and engagement assessed as key secondary outcomes to capture clinically important differences between the modalities.

Cost and accessibility strengthen the comparison and are key factors supporting PRT. A scoping review of low-cost robotic cats and dogs identified affordability and device availability as key determinants of who can benefit, noting issues such as short follow-up periods, inconsistent protocols, and insufficient reporting of implementation outcomes [14]. However, economic arguments should not only consider low unit price, but also the total cost of each modality: for AAT, this includes handler fees, animal training and care, insurance, and infection-control overhead; for PRT, it includes device acquisition, batteries and consumables, cleaning and disinfection, maintenance and replacement, and staff training and time costs. Costs should be measured in units of clinically meaningful reductions in BPSD domains (e.g., agitation), and incremental costs per quality-adjusted life-year (QALY) could also be estimated. Decision-makers can also weigh costs against benefits rather than assuming that a lower purchase price equates to a higher value. Such in-depth implementation science analyses are largely lacking in the current literature. These limiting factors are important in LTC settings given persistent staff shortages, turnover, and budget constraints. Unfortunately, unequal access to AAT limits its real-world impact regardless of efficacy.

Because implementation is central to the case for PRT, evaluation should use an established implementation-science framework to systematically assess its real-world feasibility and uptake. Proctor and colleagues' taxonomy of implementation outcomes (acceptability, adoption, appropriateness, feasibility, fidelity, penetration/reach, implementation cost, and sustainability) is one option. These metrics should be measured alongside clinical outcomes [22]. In practice, a head-to-head trial can assess acceptability and appropriateness through patient, family, and staff reports; adoption and penetration through the proportion

of eligible units and patients initiating each modality; fidelity through the match between delivered and protocolized sessions; feasibility and staff burden through time-and-motion capture; implementation cost as described above; and sustainability through continued use and device serviceability at follow-up. Without these metrics, conclusions regarding the implementation advantages of PRT over AAT will lack sufficient support.

This field urgently needs practical, head-to-head comparative-effectiveness studies in LTC and geriatric settings. For example, a cluster-randomized, non-inferiority design study across LTC units/facilities, using standardized treatment doses in two groups and including an attention-matched human social interaction control group, could test whether PRT is comparable to AAT in treating BPSD domains (e.g., agitation), while also capturing the other factors that influence implementation. Such trials should pre-specify a non-inferiority threshold for the primary outcome, include pre-specified secondary outcomes (e.g., depression, anxiety, sleep, quality of life, engagement), track adverse events and medication changes, and record Proctor et al.'s implementation outcomes (e.g., uptake, completion, staff workload, device maintenance, cost). Ethical considerations should be incorporated into the study design, including assessing participant preferences, assent, and understanding of the intervention. Protocols should address potential risks of deception, over-attachment, and substitution for human contact, and clearly define safeguards and staff guidance. Measuring participants' perceived dignity, autonomy, and emotional well-being will contribute to improving the rigour and legitimacy of the work.

For practitioners, the most valuable questions are not merely whether PRT is statistically non-inferior to AAT, but rather under what circumstances PRT is a worthwhile alternative, which patients benefit most, and which aspects of care are preserved or sacrificed when a robotic companion replaces a live animal. Facilities using robotic pets are unlikely to believe that robots are more effective than live animals. A more plausible explanation is that they believe the accessibility, consistency, and ease of deployment of robots are sufficient to compensate for some loss of therapeutic efficacy. Non-inferiority comparisons can determine whether PRT retains the key advantages of AAT, while comparative-effectiveness and implementation outcomes can clarify when and to which populations each approach is more suitable.

Currently, maintaining a balanced stance is necessary: both AAT and PRT may produce slight improvements in certain dementia and BPSD-related symptoms (especially agitation), but their efficacy remains uncertain due to heterogeneity in trial quality and intervention design [7–11]. If PRT proves to be non-inferior to AAT in some aspects of BPSD, and implementation data support successful scalability, then it could reduce reliance on medications with limited efficacy but high risks, and shift the focus of research in the field from whether these interventions are

effective to how to responsibly implement them on a large scale, and in which settings and to which populations.

ETHICAL STATEMENT

Ethics Approval

Not applicable.

Declaration of Helsinki STROBE Reporting Guideline

Not applicable.

DATA AVAILABILITY

No data were generated from this study.

AUTHOR CONTRIBUTIONS

Conceptualization, CZ; Writing—Original Draft Preparation, CZ; Writing—Review & Editing, CZ, SD, NF.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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