

1        **Application of the Robotic Seal PARO, a Neurological Biofeedback Medical**

2        **Device, to Elderly Persons with Dementia at Home: An Analysis from Seven Cases**

3        Kaoru Inoue<sup>1</sup>, Chiyomi Yatsu<sup>2</sup>, Daryl Patrick G. Yao<sup>1</sup>, Chihiro Sasaki<sup>3</sup>, Kazuyoshi Wada<sup>4</sup>,  
4        Takanori Shibata<sup>5</sup>

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6        <sup>1</sup> Graduate School of Human Health Sciences, Tokyo Metropolitan University, 7-2-10  
7        Higashiogu, Arakawa-ku, Tokyo, 116-8551, Japan.

8        <sup>2</sup> Fraser Health, Suite 400, Central City Tower, 13450 – 102nd Avenue, Surrey, BC  
9        V3T 0H1, Canada

10       <sup>3</sup> Nursing Station Hanakirin, 7-2-5-102, Higashikasai, Edogawa-ku, Tokyo, 134-0084,  
11       Japan.

12       <sup>4</sup> Graduate School of Systems Design, Tokyo Metropolitan University, 6-6,  
13       Asahigaoka, Hino city, Tokyo, 191-0065, Japan.

14       <sup>5</sup> Human Informatics and Interaction Research Institute, National Institute of  
15       Advanced Industrial Science and Technology (AIST), 1-1-1 Umezono, Tsukuba,  
16       Ibaraki 305-8568, Japan

17  
18       Corresponding author: Kaoru Inoue ([inoue@tmu.ac.jp](mailto:inoue@tmu.ac.jp))

19 **ABSTRACT**

20 Background: In Japanese society today, many elderly persons with dementia (EPWD) are  
21 living at home. This research focused on the family members of EPWD who provide  
22 informal care and support. The purpose of this research was (1) to analyse the potential  
23 and effectiveness of care provided by the family with the use of the robotic seal PARO, a  
24 neurological biofeedback medical device, and (2) to identify and prioritise problems when  
25 utilising PARO in the home context.

26

27 Methods: This study employed a mixed-methods approach involving observational data  
28 and interviews. Family members of seven households caring for EPWD were asked to  
29 use the seal robot “PARO” as a means to provide care. The family caregivers used PARO  
30 at home for more than three times per week, over one to three months. At the initial visit,  
31 an individualised purpose of PARO was established. Family members were taught how  
32 to operate PARO and how to facilitate PARO use. Research data were collected at initial  
33 and subsequent monthly visits, in the form of families’ observational feedback, interviews,  
34 and direct assessment of the subjects. Collected data were analysed quantitatively and  
35 qualitatively.

36

37 Results: Five out of the seven elderly persons reacted positively to PARO and achieved  
38 their intervention goals. Acceptance of PARO use depended on the positive interaction  
39 observed at the initial encounter, which led to continued interest later on. On the other  
40 hand, for the subjects where “encouragement was required to trigger interaction” at the  
41 initial encounter, their subsequent interest may either increase or decrease. Furthermore,  
42 observed activities with PARO use for all families were conversations and physical touch  
43 to PARO. Some families facilitated reminiscence and intellectual activities.

44

45 Conclusions: The study indicated that the effect of PARO application at home is possibly  
46 influenced by the participants' initial level of interest towards PARO. It is still crucial to  
47 perform careful observation and assessment of the benefit of PARO before adapting the  
48 treatment strategy. The families need specific advice from relevant healthcare  
49 professionals, such as occupational therapists, to maximise the use of PARO. This implies  
50 that effective robotic care at home requires professional support.

51

52 Keywords: Dementia Care, Home Care, Family Caregiver, User Acceptance, Seal Robot,  
53 Person-Centred Care, Occupational Therapy, Japan

54

55 **BACKGROUND**

56 Many of the Japanese elderly wish to live the rest of their lives in environments familiar  
57 to them, even if they may become heavily in need of long-term care. The Japanese  
58 Ministry of Health, Labour and Welfare (MHLW) established a scheme called ‘the  
59 Community-based Integrated Care System’ to ensure adequate provision of health care,  
60 nursing care, prevention, housing, and livelihood support [1].

61

62 According to Chiao's systematic review regarding the burden on families of elderly  
63 persons with dementia (EPWD), numerous studies highlighted the importance of  
64 educating families [2]. In Japan, the burden of care carried by families who care for  
65 EPWD has become a major problem. In 2006 the Act on the Prevention of Abuse against  
66 the Elderly and the Support of Elderly Caregivers, which focuses on the protection of  
67 human rights for the elderly, came into force [3]. Since this law’s enforcement, the  
68 Japanese government has been collecting data related to elderly abuse. In a nationwide  
69 survey in 2018, caregivers’ fatigue and stress were the number one causes of domestic  
70 abuse. The Japanese government, organisations in support of persons with dementia, and  
71 researchers have asserted the necessity to reduce the burden of giving care, provide  
72 psychological support, and educate family caregivers for families living with EPWD. A

73 health care provider (HCP) historically played a leading role in this context. However,  
74 considering steady increase in the number of reported abuse from 273 cases in 2006 to  
75 1723 cases in 2016, including abuses committed by family members to EPWD, it shows  
76 that the current system alone cannot easily solve the problem.

77

78 The support provision as stipulated within the social policy is reasonable. However, it is  
79 necessary to review the contents and process of support. It is important to educate family  
80 members the knowledge to care for EPWD. However, without a specialised background,  
81 it is a challenge for a layperson to understand theories and practices meant for HCP.  
82 Therefore, easily understandable care methods that everyone can practice are essential.

83

84 The emergence of an ageing society led to an increased number of EPWD. As of 2017,  
85 Japan had reached the world's highest number of elderly people, necessitating the need  
86 for a strategy to address dementia and its symptoms [4]. According to the MHLW,  
87 healthcare staff required for fiscal 2025 are approximately 2.45 million people, with an  
88 expected shortage of about 0.34 million. Thus, providing adequate long-term care  
89 services may become a challenge [5]. "Hands-on care" alone may not be adequate to meet  
90 the demand, hence adapting "care by device" can be a viable strategy to compensate for

91 the labour shortage.

92

93 The Government of Japan promotes the development and practical use of robots under  
94 the “new robot strategy” [6]. Moreover, the use of robots in the medical and nursing field  
95 is flourishing, becoming one of the major industries in Japan. While there exist numerous  
96 clinical trials on medical robots, most of them, especially those using a Randomised  
97 Controlled Trial (RCT) design, have focused on the Japanese-made baby seal robot  
98 "PARO", a neurological therapeutic medical device certified by the United States Food  
99 and Drug Administration [7].

100

101 At present, PARO is used in the medical and welfare fields in various developed countries  
102 and regions such as the United States, Canada, Europe, Asia, and Oceania. According to  
103 Kang’s systematic review, PARO is effective in improving QOL, emotions, social  
104 interaction, and reducing the amount of medication for neuropsychiatric symptoms [8].  
105 In Hung’s scoping review, reducing negative feelings and problematic behaviour as well  
106 as improving social interaction and eagerness of caregiver are the benefits of using PARO  
107 [9]. Several studies found that the use of PARO among EPWDs could impact different  
108 aspects of the EPWD such as improved quality of life and enjoyment, facial expression

109 and communication, mood, and diminished stress, anxiety, and use of antipsychotic  
110 medication, and neutral affect [10-15]. Additionally, PARO can positively influence the  
111 physical activation of EPWDs without altering their sleep patterns [16]. Thus, several  
112 studies recommended PARO for people with mild to moderate agitation brought about by  
113 dementia and community-dwelling seniors who attend day-care programs [13, 17].

114

115 Despite the numerous studies, most of these were obtained from healthcare facilities  
116 administered by trained HCPs. Furthermore, the only research conducted within one's  
117 natural environment did not look into the effects of using PARO solely at home as it was  
118 a combination of daytime PARO use in a day-care centre and home [13]. Families of  
119 EPWD are already using everyday technology such as alarmed sensors and internet but  
120 the everyday use of robots are not as common [18,19]. Thus, it is of benefit to consider  
121 PARO use, as the use of robots has the potential to contribute greatly to the extension of  
122 community living and become one of the solutions to providing high-quality home care.

123

124 To use a neurological biofeedback medical robot at home, the family must be able to  
125 operate it easily and effectively. Adapting the Person-Centred Care (PCC) approach to  
126 improve the quality of care is a possible approach for both family members and HCPs as

127 the theory is not exclusive to the experts. PCC is a theory of dementia care proposed by  
128 British social psychologist Tom Kidwood. He believes that personhood can be maintained  
129 by meeting five needs namely: Comfort, Identity, Attachment, Occupation, and Inclusion  
130 [20]. From the result of the abovementioned studies, introducing robots to family care can  
131 potentially meet the five needs of PCC by engaging with the subjects. Furthermore, it is  
132 possible to demonstrate the difference between good care and not so good care from  
133 realistic examples while considering the individual circumstances of the family.  
134 EPWDs often find it difficult to accurately convey their feelings to others, therefore it is  
135 crucial for the caregiver to objectively observe the person to determine the condition when  
136 providing care. EPWDs also present with reduced judgement skill to make every-day life  
137 decisions, therefore, to ethically provide care by a robot, the viewpoint of the EPWD must  
138 be considered. PCC is an approach to dementia care that can be applied in two  
139 perspectives: as a way of supporting families and as an education method.

140

141 This study aimed to examine the possibilities of care by the family using the neurological  
142 biofeedback medical robot, PARO. The purpose of this research was (1) to analyse the  
143 potential and effectiveness of care provided by the family with the use of PARO, and (2)  
144 to identify and prioritise problems when utilising PARO in the home context.



145

146 **METHODS**

147 Design:

148 A mixed-methods approach involving standardised assessments, observational data, and  
149 interviews with a family member of an EPWD was employed to investigate the  
150 possibilities of utilising robots as part of home care.

151

152 Tools and Materials:

153 In this research, a neurological biofeedback medical robot called “PARO” (Intelligent  
154 Systems Inc.) was used (Fig. 1). PARO is a baby seal shaped robot (9th generation, about  
155 57cm, about 2.5 kg) developed at the National Institute of Advanced Industrial Science  
156 and Technology (Japan).

157

158 Guided by the notions behind animal-assisted therapy, a therapy robot PARO was  
159 developed to facilitate the users’ psychological, physical and social wellbeing [21].

160 PARO’s functions are described as following: PARO does not speak a language or walk,  
161 but it is capable of making an animal-like cry, moves its head and legs, and blinks. With  
162 excellent artificial intelligence, it has a learning function such as remembering the name

163 of a person and endears itself to its owner with cute gestures and cries. Also, high safety  
164 standards through antibacterial processed fur and magnetic shielding function enable  
165 PARO to be used in intensive care settings [22].

166



167

Figure 1: PARO

168

169

170 Participants:

171 The participants of this research are home-dwelling EPWD who live with and receive  
172 care from their families. The inclusion criteria were set as elderly (over age 65)  
173 individuals diagnosed with dementia, with no severe consciousness disorder, residing at

174 home with a family member, and who, by assessment of a qualified HCP, is expected to  
175 benefit from using PARO. Other criteria such as the severity of cognitive deficits were  
176 not set.

177

178 Recruitment:

179 The research team distributed a recruitment brochure that stipulated an overview of the  
180 research amongst dementia support groups in the Tokyo metropolitan area and Long-  
181 Term Care Insurance case managers' gatherings. Interested volunteer participants  
182 contacted the principal researcher to schedule an initial home visit. Both the principal  
183 investigator (PI) and the case HCP conducted the initial home visit. The PI explained the  
184 content of research as well as the known effectiveness of PARO before obtaining the  
185 participants' agreement. Once the participant agreed, PARO was presented to the research  
186 subject to examine for any negative reaction. Negative reactions such as anxious  
187 expression, sad expression, disturbing behaviour, and anger towards PARO were  
188 perceived as an indication of their refusal to participate. These individuals were then  
189 excluded from further participation. informed consent was obtained from participants and  
190 family.

191

192 Data Collection

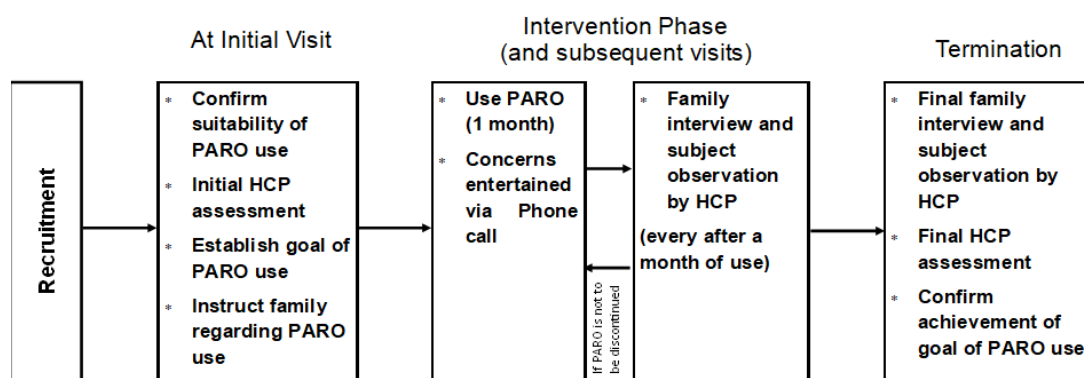
193 Once the research subject's participation in the trial was ascertained, the PI, the case HCP,  
194 and their family collaboratively established a goal for using PARO in light of the  
195 previously explained effectiveness of PARO [10,12,13]. Then, the PI and the case HCP  
196 completed standardised assessments for the subjects and collected information from the  
197 family including the subject's sex, diagnosis, level of required care, and history of  
198 experience with pets. At the end of the initial visit, the PI advised the family regarding  
199 the set-up, operation, maintenance, and timing of use of PARO. The following  
200 recommendations were given:

- 201 (1) PARO is placed on a spot easily seen by the subject,
- 202 (2) provide verbal and gestural prompts to encourage interaction with PARO, and
- 203 (3) allocate time to communicate with the subject about PARO among other topics.

204 The family was encouraged to contact the PI at any time for consultation. The family then  
205 proceeded to present PARO to the subject at least three times per week for one month. At  
206 every month interval, the case HCP conducted home visits to monitor the subjects through  
207 observation and interviews with family caregivers regarding the subject's general  
208 condition, numbers and ways of encounter with PARO, and the subject's reaction to  
209 PARO. At the final visit, in addition to the above-mentioned monthly procedures, the case

210 HCP repeated the standardised assessments and conducted a semi-structured informal  
 211 interview regarding PARO use. Key questions for jumpstarting the conversation are  
 212 found in Supplement 1. The family’s comments were recorded through an audio recorder,  
 213 which was later transcribed. The process of data collection was synthesised as shown in  
 214 Figure 2.

215



216

217

Figure 2 Process of data collection

218

219 Outcome measures and methods of analysis

220 ***Standardised assessment:***

221 A series of standardised assessments were conducted at the start and the end of PARO  
 222 intervention. The assessments included: Mini-Mental Status Examination-Japanese  
 223 (MMSE-J), Nishimura’s Activity of Daily Living Scale (N-ADL), Dementia Behaviour  
 224 Disturbance (DBD) Scale, and Zarit Burden Interview [23-26]. The MMSE-J is an official

225 Japanese edition of the Mini-Mental State Examination, a screening test for detecting  
226 dementia wherein a grade lower than 23/30 may indicate dementia [27]. The N-ADL is a  
227 simple Japanese test that evaluates the level of ADL independence by observing the  
228 behaviour of an elderly person with suspected dementia wherein a full score of 50  
229 indicates normal [24]. The DBD Scale by Baumgarten is a 28-items, 5-point scale  
230 totalling 112 points used to observe the behaviour of people with dementia [25]. In this  
231 study, the Japanese version of DBD was used [28]. Lastly, the Zarit Burden Interview is  
232 an assessment tool that objectively evaluates the feeling of burden experienced by  
233 caregivers of people with dementia and other conditions requiring assistance [26]. In this  
234 research, we used the Japanese version standardised by Arai [29].

235

236 ***Interview with family caregiver:***

237 An inductive analysis method was employed to categorise collected qualitative data.  
238 First, the PI transcribed the family caregivers' comments recorded in the IC recorder, then  
239 selected key sentences or keywords rephrased into short sentences (codes). These codes  
240 were synthesised into sub-categories, then into categories. Three experienced HCPs  
241 collectively reviewed these codes and categories to clarify any uncertainty. The PI revised  
242 short sentences until a unanimous agreement was reached.

243

244 ***Observation:***

245 The subject's behaviours, which include (1) state of interactions with PARO and (2)  
246 changes in interest towards PARO, were observed and documented by the case HCPs  
247 during monthly visits. This was supplemented by reports extracted from the interviews  
248 with the family caregivers. The resulting data were analysed qualitatively for all cases to  
249 identify similarities and differences.

250 (1) **The subjects' behaviour:** To categorise the behaviour of the subjects, the  
251 Dementia Care Mapping (DCM) evaluation framework was employed [30]. Two  
252 HCPs with Advanced Dementia Care Mapper qualification coded the observed  
253 behaviour of participants from 23 pre-defined Behaviour Category Code (BCC)  
254 of DCM [31]. Examples of the BCC are:

- 255 • A (Articulation): Interaction with others verbally or otherwise,
- 256 • G (Going back): Reminiscence and life review,
- 257 • I (Intellectual): The use of intellectual abilities and
- 258 • O (Objects): Displaying attachment to or relating to inanimate objects [31].

259 The definition of PCC was considered for determining whether a subject's  
260 responses were positive or negative.

261 (2) **The subjects' changes in interest**: The subject's level of interest toward PARO  
262 was graded using timeline graphs. A five-level grading scale was used to  
263 categorise the observation namely:

- 264 ✓ 1- Completely ignore or reject PARO;
- 265 ✓ 2- Even if presented and encouraged, hardly interacts with PARO;
- 266 ✓ 3- If presented and encouraged, interact with PARO but without volitional  
267 movement
- 268 ✓ 4- If presented with PARO, touch voluntarily and;
- 269 ✓ 5- Requests for PARO use and touches PARO voluntarily

270 Using the agreed grading scale, the PI and three HCPs plotted the subjects' level  
271 of interest every month.

272

## 273 **RESULTS**

274 The subjects' profile and the result of standardised assessments are shown in Table 1.

275 Out of ten families who volunteered to participate, seven families were included in this  
276 research. Subjects were 6 female and 1 male. Family caregivers include 4 sons, 2  
277 daughters, and 1 daughter-in-law.

278



279 At the beginning of the research, the MMSE score ranged from 4 to 21 points, the N-ADL  
280 score from 2 to 46 points, the DBD from 12 to 40 points, and the Zarit care burden score  
281 from 14 to 40 points. Throughout the data collection period, none of the subjects was  
282 diagnosed with any new medical conditions, nor was their existing medicines changed.

283 **Table 1: Participants' profile and the result of standardised assessments**

	<b>Case 1</b>		<b>Case 2</b>		<b>Case 3</b>		<b>Case 4</b>		<b>Case 5</b>		<b>Case 6</b>		<b>Case 7</b>	
<b>Age/Sex</b>	86/F		82/F		97/F		79/F		97/M		85/F		85/F	
<b>Diagnosis &amp; Care level*</b>	Alzheimer's Dementia (level 1)		Alzheimer's Dementia (level 1)		Alzheimer's Dementia (level 4)		Alzheimer's Dementia (level 3)		Alzheimer's Dementia (level 4)		Dementia (level 4)		Alzheimer's Dementia (level 1)	
<b>Experience with pets</b>	Had a dog		Had a dog and cat		Had a dog		Had a dog, cat, & bird		Had various pets		Likes animals		Had a pet (but dislikes animal)	
<b>Caregiver</b>	Daughter-in-law		Eldest daughter		Eldest son		Eldest Daughter		Eldest son		Husband & eldest son (lives nearby)		Eldest son	
<b>Caregiver's age</b>	55		55		62		54		54		88, 62		61	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
<b>MMSE-J</b>	16	17	21	NT	4	10	13	5	15	19	5	NT	14	14
<b>N-ADL</b>	42	36	46	NT	2	15	41	40	14	14	25	27	25	31
<b>DBD</b>	23	23	17	NT	12	20	35	35	19	14	12	11	40	18
<b>Zarit</b>	14	13	29	NT	27	28	40	35	33	30	12	7	33	12

284 \*Care level: Japan's classification system wherein level 5 is the most severe.

285 NT = not tested.

286 The purpose of introducing PARO to the participants included: to increase spontaneous  
287 activity (5 cases), to reduce uneasiness/restlessness (4 cases), to feel uplifted (3 cases), to  
288 feel soothed (2 cases), and to reduce family's burden of supervision (2 cases). An  
289 overview of the subjects' goal achievement is shown in Table 2. The cases who achieved  
290 their goal demonstrated interest and curiosity toward PARO from the initial encounter  
291 through displaying the following common behaviours: (1) looking at PARO with  
292 enthusiasm and (2) leaning forward to touch PARO with or without encouragement from  
293 others. These individuals were noted to interact with PARO voluntarily, smiled more, and  
294 communicated with their families more.

295

296 In observing the subjects' interaction with PARO, (A) verbal communication and (O)  
297 relating to PARO were common to all cases. Additionally, during the interview, family  
298 caregivers of two cases (case 1, 3) reported that the use of PARO reminded the subject of  
299 their experience in caring for a child or their pet (G). The caregiver of case 3 also reported  
300 that the subject showed an increased level of curiosity by asking questions (I), such as  
301 "where do seals live".

302


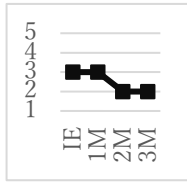
303 Regarding the change in the level of interest towards PARO, cases that achieved their

304 goal either maintained a high level of interest or demonstrated a positive shift of interest.  
305 These subjects tend to talk with PARO, touch voluntarily or with minimal encouragement,  
306 lean towards PARO, and gaze at PARO with a smile and a relaxed facial expression.  
307 Individuals who demonstrated positive traits behaved as if caring for a child, talked about  
308 PARO with family and acquaintances, requested to see PARO, gazed at PARO with a  
309 smile, and petted PARO.

310

311 Discontinuation of the use of PARO was on the first month for two families, the second  
312 month for another two families, and on the third month for three families. Reasons for  
313 discontinuation were poor physical condition of the subject (4 cases), loss of interest in  
314 PARO (2 cases), and the family becoming too busy (1 case).

315 **Table 2: Results of observation**

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7
<b>Goal achievement</b>	Not achieved	Achieved	Achieved	Not Achieved	Achieved	Achieved	Achieved
<b>BCC</b>	A, G, O	A, O	A, G, I, O	A, O	A, O	A, O	A, O
<b>Change in Interest*</b>							

316 <sup>1</sup>BCC: A (articulation) = interaction with others, G (going back) = reminiscence and life review, I (intellectual) = use of intellectual abilities, O  
 317 (objects) = displaying attachment to or relating to inanimate objects.

318 <sup>2</sup>Change in interest: 5= requests for and touch PARO voluntarily, 4= touch PARO voluntarily if it is presented, 3= interact with PARO if  
 319 encouraged by others, 2= hardly interacts with PARO even if encouraged, 1= completely ignore and rejects PARO.

320 \*Scored at initial visit followed by monthly visits

321

322 The caregivers reported that subjects displayed a positive reaction to PARO (14 labels)  
323 in the first month. However, this positive reaction was less noted in subsequent interviews  
324 at the second (4 labels) and third (3 labels) months. Improvement in behaviours, which  
325 include increased frequency of interaction and diminished agitations, were also reported  
326 within the first (4 labels) and second (4 labels) months only. Additionally, the content of  
327 reported behaviour considered as an ‘improvement’ was related to the volume or content  
328 of conversations done amidst PARO. The trend observed can be because it was easier for  
329 the families to recognise any changes of the subjects’ behaviour and to think of ways to  
330 encourage the use of PARO during the first month as compared to other months. This can  
331 also mean that they have been enacting same patterns of encouragement in subsequent  
332 months thus, no longer thought that it is still worthwhile to report it. Reports concerning  
333 negative reactions, on the other hand, emerged from the second (4 labels) and third (3  
334 labels) months. Quotations supporting the categories are shown in table 3.

335

336 The caregivers themselves also received direct and indirect benefits from interacting with  
337 PARO. They got more time to interact with the subject, to do chores, and to simply feel  
338 good and relaxed. A caregiver shared, “I was able to talk about fond memories with the  
339 subject in PARO’s presence.” However, during the first month, the operation of PARO

340 was a challenge. Five inquiries (from three families) were received concerning charging  
341 PARO and locating the switch of PARO. These issues were resolved as familiarity with  
342 PARO was established in the subsequent months. While the caregivers enjoyed the use  
343 of PARO, several caregivers of subjects who did not achieve their goal voiced out the  
344 inapplicability of PARO on the second and third months. One caregiver even blamed their  
345 self as they said, “It was a shame that I wasn’t able to encourage to use PARO very well”.

346 Caregivers’ experiences can be found in table 3.

347 **Table 3: Family caregiver’s comments regarding PARO use**

<b>Subject’s Reaction to PARO</b>			
	<b>Categories</b>	<b>Comments</b>	<b>Labels</b>
<b>After 1 Month</b>	<b>Positive reaction</b>	<ul style="list-style-type: none"> <li>• “Talking PARO is like talking to a child”</li> <li>• “She sat up and reached to pet PARO”</li> </ul>	<b>14</b>
	<b>Improved behaviour</b>	<ul style="list-style-type: none"> <li>• “She stopped wandering around and stayed seated”</li> <li>• “She became more accepting of care aids’ assistance”</li> </ul>	<b>4</b>
<b>After 2 Months</b>	<b>Positive reaction</b>	<ul style="list-style-type: none"> <li>• “She appears to love PARO very much”</li> <li>• “She often asks for PARO’s whereabouts”</li> </ul>	<b>4</b>
	<b>Improved behaviour</b>	<ul style="list-style-type: none"> <li>• “She talked more frequently. The conversation became gentler”</li> </ul>	<b>4</b>
	<b>Negative reaction</b>	<ul style="list-style-type: none"> <li>• “She said I should play with PARO instead”</li> </ul>	<b>1</b>
<b>After 3 Month</b>	<b>Positive reaction</b>	<ul style="list-style-type: none"> <li>• “She is always petting PARO”</li> </ul>	<b>3</b>
	<b>Negative reaction</b>	<ul style="list-style-type: none"> <li>• “Appears to not like PARO”</li> </ul>	<b>3</b>

<b>Family’s experience with PARO</b>			
	<b>Categories</b>	<b>Comments</b>	<b>Labels</b>
<b>After 1 Month</b>	<b>Felt soothed</b>	<ul style="list-style-type: none"> <li>• PARO was so cute</li> <li>• PARO is good enough to call it a pet</li> </ul>	<b>4</b>
	<b>Increased interaction with subject</b>	<ul style="list-style-type: none"> <li>• We talked about our old pet</li> <li>• We played a trivia game about seals</li> </ul>	<b>1</b>
	<b>Maintenance and Function</b>	<ul style="list-style-type: none"> <li>• PARO doesn’t charge sometimes</li> <li>• PARO was heavier than I thought</li> </ul>	<b>2</b>
	<b>Benefits for caregiver</b>	<ul style="list-style-type: none"> <li>• PARO gave me time to complete chores</li> </ul>	<b>1</b>
	<b>Reduced feeling of guilt</b>	<ul style="list-style-type: none"> <li>• I can leave the subject without feeling like neglecting her</li> </ul>	<b>1</b>
<b>After 2 Months</b>	<b>Felt soothed</b>	<ul style="list-style-type: none"> <li>• I like PARO more than the subject</li> </ul>	<b>4</b>
	<b>Increased interaction with subject</b>	<ul style="list-style-type: none"> <li>• Reminded me of how my mother used to be</li> </ul>	<b>1</b>
	<b>Benefits for caregiver</b>	<ul style="list-style-type: none"> <li>• I felt like I was being useful</li> </ul>	<b>2</b>
	<b>Reduced feeling of guilt</b>	<ul style="list-style-type: none"> <li>• The amount of care remains the same, but my feeling of guilt is less</li> </ul>	<b>1</b>
	<b>Not applicable for use</b>	<ul style="list-style-type: none"> <li>• The subject just isn’t interested in PARO</li> </ul>	<b>1</b>
<b>After 3 Months</b>	<b>Felt soothed</b>	<ul style="list-style-type: none"> <li>• I felt soothed by PARO. It may also have a positive effect on the subject</li> </ul>	<b>2</b>
	<b>Benefits for caregiver</b>	<ul style="list-style-type: none"> <li>• I felt like I was useful to the subject</li> </ul>	<b>1</b>
	<b>Not applicable for use</b>	<ul style="list-style-type: none"> <li>• The subject did not use PARO. Maybe I did not facilitate it correctly</li> </ul>	<b>1</b>

348 \*\*All reported numbers of labels are cumulative



349 **DISCUSSION**

350 Effectiveness of PARO Activities:

351 Five subjects reacted positively to PARO and achieved their set intervention goals. Based  
352 on the characteristics of the positive results, it is possible to infer that activities using  
353 PARO could expand the potential of people who are interested in PARO.

354

355 The result of this research supports the previously reported efficacy of PARO. Previous  
356 research findings regarding the use of PARO revealed that it is effective in (1) increasing  
357 spontaneous activity, (2) reducing uneasiness/restlessness, (3) respiting from the burden  
358 of supervision for family caregivers, (4) feeling soothed, and (5) feeling uplifted.  
359 Furthermore, previous research in topics related to the use of PARO resulted in  
360 experiencing a desirable difference in terms of agitation, mood, emotion (joyfulness,  
361 loneliness), stress, anxiety, physical activation, facial expression, and communication [8-  
362 17].

363

364 Moreover, PARO exhibits the potential to spark activities that meet the needs enumerated  
365 by the PCC philosophy [30]. The effect of utilising PARO in this research positively  
366 impacted the subjects' conditions. PARO is expected to decrease care burden and enable

367 improved dealings with the subjects. Activities with PARO facilitate the subjects' feeling  
368 of ease (comfort), and the subjects in a calm state of mind reminiscing about their past  
369 life events (identity), which then increases communication with families and offers  
370 occasions to feel connected as a family member (attachment and inclusion). In cases  
371 where subjects were conscious of taking care of PARO, the need for 'occupation' was  
372 fulfilled. Meeting the five needs as identified in the PCC approach is said to improve the  
373 well-being of people with dementia [30]. We identified that effective use of PARO at  
374 home can be valid as a tool for care provision.

375

376 Factors identified for PARO use:

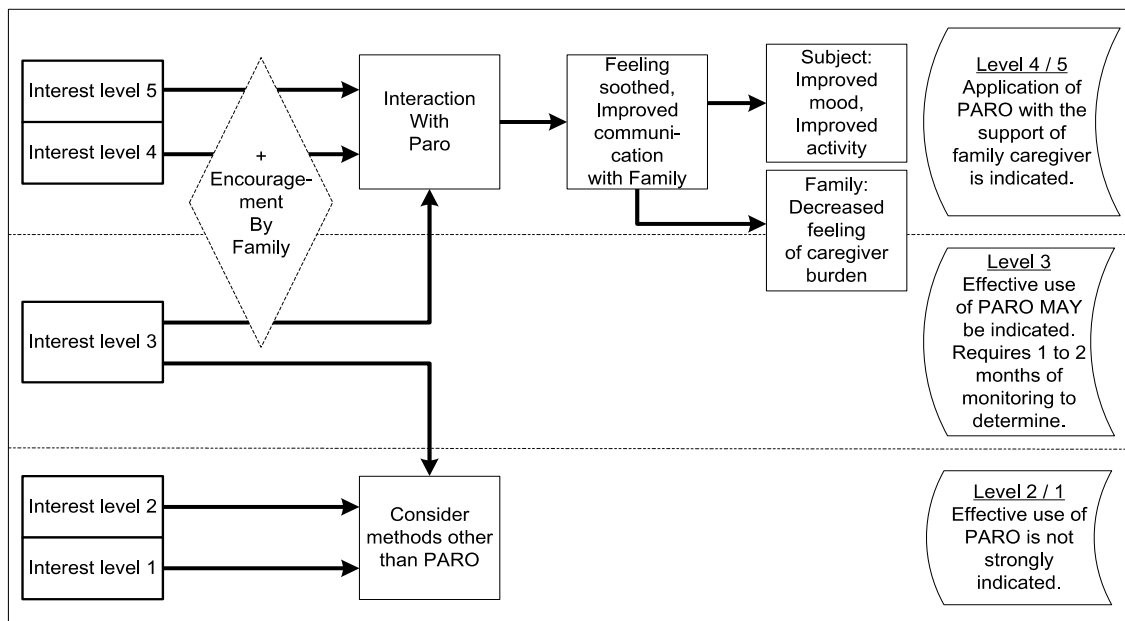
377 From an environmental perspective, the use of PARO increased time spent being active,  
378 thereby obtaining healing and fun, creating a constructive cycle of wanting to interact  
379 again with PARO. However, PARO may not be appropriate for individuals who do not  
380 exhibit any sign of interest. Since these responses were observed from the time of the first  
381 introduction or during the first month, it suggests the possibility of being able to predict  
382 the appropriateness of using PARO at the time of the first meeting. It is not reasonable to  
383 expect a positive result from PARO use with a family caregiver when PARO is rejected  
384 from the onset.

385 However, for subjects who only interacted with PARO when encouraged (scored 3) at the  
386 initial visit, level of interest may increase (cases 3 and 7) or decrease (cases 1 and 4).  
387 Hence, there should be a month trial period to confirm the subject's level of interest as  
388 the potential for effective PARO use became apparent after 2 months of use. Furthermore,  
389 when the subject's interest in PARO diminished soon after the initial encounter, extending  
390 the duration of using PARO did not improve the level of interest. Nevertheless, providing  
391 sufficient support and advice at the initial stage by a HCP may lead to more appropriate  
392 and continued use of PARO.

393

394 Figure 3 illustrates the applicability of utilising PARO as indicated by the level of subjects'  
395 reaction to PARO. Hypothesis obtained from this study should be considered from a long-  
396 term efficacy perspective.

397



398

399 Figure 3 Application of PARO use indicated by the level of the subject's interest

400

401 Supports Considered Necessary to Use PARO in a Home Care Setting:

402 During this research, we provided families with instructions and advice regarding 'A -  
 403 articulation' and 'O - objects'. It was found that positive influences that can be expected  
 404 with the use of PARO, as analysed using the BCC (DCM), were 'A' and 'O'. In addition  
 405 to responding to instructions and advice, the families might have found that encouraging  
 406 conversations (related to 'A') and interactions with PARO (related to 'O') came  
 407 spontaneously and easily. Furthermore, while the families were not taught on how to  
 408 initiate intellectual activities ('I - intellectual') and reminiscence ('G - going back') with  
 409 the participants at the initial visit, some families observed 'G' and 'I'. Hence, instructions

410 and advise related to 'G' and 'I' should be given during the initial meeting in addition to  
411 'A' and 'O', as it might help widen the scope of care by the family. By receiving  
412 instructions from HCP at the time of the introduction of PARO, it is expected that the  
413 family can expand both the variety and extent of the subjects' activities.

414

415 Two reports found that family caregivers of EPWD use everyday technology such as  
416 smartphones to support care provision [18,19]. Robot technology is currently used for  
417 home alliances, with an expectation to expand into the field of dementia care. Given this,  
418 the HCP could support successful participation in the activity by discussing proper  
419 handling procedures to the family, setting-up PARO in a manner tailored to the subject,  
420 educating means to encourage the subject to use PARO, and clarifying the benefits of the  
421 activity. This research finding responds to the challenge posed by Hung that "Future  
422 research should pay more attention to the clinical needs of the patient population and  
423 develop strategies to overcome barriers to the adoption of PARO in order to maximise  
424 patient benefits." [9, p. 1]

425

426 The general assumption in using assistive technology under public funding in Japan is to  
427 use it only when required and discontinue as soon as it becomes unnecessary. Similarly,

428 PARO does not need to be used for a prolonged period and may be discontinued once the  
429 purpose is achieved. Judging whether the purpose is achieved is thought to be difficult  
430 for the layperson, so an evaluation by an HCP must be done before the termination of  
431 PARO. HCPs, such as occupational therapists who provide individually-tailored  
432 interventions, can generate better outcomes in dementia care [32,33].

433

434 In summary, this investigation has shown that when PARO is used in-home care,  
435 individuals who displayed an active interest in PARO from the beginning would  
436 voluntarily increase the time spent with PARO, leading to a decrease in BPSD.  
437 Furthermore, the above effects are augmented further when care is provided by a family  
438 member, with the support of a HCP involved in dementia care. The fundamental response  
439 to BPSD depends on matters like environmental adjustment, the caregiver's facial  
440 expression, and the appropriateness of displayed behaviour. Results showed that when an  
441 object such as PARO is introduced, the EPWD naturally becomes calm and proactively  
442 makes time to spend with it. Hence, PARO can be considered an effective support tool  
443 for family care.

444

445

446 Limitations:

447 It should be noted that this report is a summary of a study of seven cases that were  
448 recruited through a public notice, so the participating families had positive attitudes as  
449 caregivers, and the result should be interpreted in consideration of it. Accordingly, the  
450 benefits observed may not apply to all cases. In the future, it will be necessary to use a  
451 larger number of subjects to investigate ways of providing more effective and practical  
452 support. Additionally, it will be helpful to explore ways of combining home-based and  
453 day-care facility services.

454

455 **CONCLUSION**

456 Five participants showed active interest and interaction from the first meeting. For these  
457 subjects, PARO was able to achieve its purpose. PARO may not be an ideal intervention  
458 for people who exhibit little interest at the time of introduction. This study found that the  
459 characteristics of individuals who could potentially benefit from PARO are distinguished  
460 not according to the severity of dementia but by one's level of interest in PARO  
461 (recognising PARO as cute and being willing to touch it actively). In the context of family  
462 care, PARO is expected to elicit an active engagement with itself leading to the reduction  
463 of BPSD and burden on caregivers. Rather than just handing PARO over to families,

464 HCPs, such as occupational therapists, should teach families how to use PARO  
465 effectively, support the process of encouragement to use PARO, and support the decision  
466 of when to terminate the use of PARO.

467

468 **List of Abbreviations**

469 MHLW: Ministry of Health, Labour and Welfare

470 EPWD: Elderly Persons with Dementia

471 HCP: HealthCare Professional

472 RCT: Randomised Controlled Trial

473 PCC: Person Centred Care

474 MMSE-J: Mini-Mental Status Examination-Japanese

475 N-ADL: Nishimura's Activity of Daily Living Scale

476 DBD: Dementia Behaviour Disturbance Scale

477 DCM: Dementia Care Mapping

478 BCC: Behaviour Category Code

479 BPSD: Behavioural and Psychiatric Symptoms of Dementia

480 PI: Principal Investigator

481



482 **Declarations**

483 Ethics approval and Consent to Participate

484 This study was approved by the Tokyo Metropolitan University Ethics Review Board  
485 (approval number: HINO-159), who has authority over the author. The experiment  
486 protocol for involving humans was in accordance to the guidelines of Tokyo Metropolitan  
487 University and the Declaration of Helsinki. The research team provided verbal and written  
488 explanations and obtained consent from participants and families. In particular, it clearly  
489 communicated to the families, both verbally and written, that their privacy is protected,  
490 PARO does not have to be encouraged when participants are in poor health, and that even  
491 after consenting, participation can be stopped at any time if the subject indicates refusal.

492

493 Consent for Publication

494 Not Applicable

495

496 Availability of data and materials

497 The datasets generated and/or analysed during the current study are not publicly available  
498 to protect the participants' right to privacy and confidentiality but are available from the  
499 corresponding author on reasonable request.

500

501 Competing interest

502 TS who invented PARO was not involved in tasks directly influencing the clinical data  
503 collection and analysis. All other authors declare no conflict of interest

504

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509 conduct of this research.

510

511 Author's' contributions

512 KI, KW, CS, and TS were involved in establishing the research design. With the  
513 assistance of CS, KI facilitated recruitment of the subjects and data collection. KI  
514 synthesised collected data in discussion with the research team and drafted this article.  
515 CS, CY, and DPGY reviewed and revised the content of this article. All authors read and  
516 gave permission for this version to be submitted for publication. All authors are  
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